THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

Plaintiff DePuy Mitek's Memorandum in Support of its Motion *In Limine* (No. 1) To Exclude Evidence Regarding CETR Testing

Plaintiff, DePuy Mitek, Inc. ("Mitek") moves *in limine* to exclude evidence regarding testing carried out by CETR on behalf of the Defendants, Arthrex, Inc. and Pearsalls, Ltd. (collectively "Arthrex") which Defendants would like to admit in support of their position that the coating on the accused FiberWire suture "materially affects the basic and novel characteristics" of the invention of the Hunter 446 Patent.

Arthrex's expert, Dr. Debi Mukherjee, states in his expert report that the CETR tests "conclusively show" that certain properties of the accused FiberWire suture are "materially affected" by the addition of coating to the suture. However, any such testimony by Dr. Mukherjee should be excluded because he admitted at his deposition that he is not an expert in explaining the results of the CETR testing and how it relates to FiberWire's coating, because he admitted that he was not familiar with the test procedures that CETR carried out, and, importantly, because he admitted that he really did *not* have opinions on whether FiberWire's

coating affected most of the tested properties. Given these stark admissions, any opinion he may now try to offer regarding the CETR testing would fail the FED. R. EVID. 702 reliability standard.

Once Dr. Mukherjee's testimony about the CETR results is excluded, Arthrex has no witness who can relate the CETR tests to the patent issues in this case, *e.g.*, whether they reflect that coating on FiberWire "materially" affects the basic and novel properties of the suture. Absent such evidence, the data will have no meaning to the jury, and there is substantial danger that the jury will be confused or misled. Any potential relevance of the data – which will be untied to the issues in the case – is greatly outweighed by the potential for prejudice, and evidence of the data should therefore be excluded pursuant to FED. R. EVID 403.

I. FACTUAL BACKGROUND

A. At Dispute Is Whether FiberWire's Coating Materially Affects the Basic and Novel Characteristics of the Invention of the Hunter 446 Patent

Mitek has accused Arthrex's FiberWire[1] products of infringing Mitek's Hunter 446 Patent. The claims of the Hunter 446 patent contain the transitional phrase "consisting essentially of." Claims using "consisting essentially of" language cover products that include the listed ingredients and can also include unlisted ingredients that do not materially affect the basic and novel characteristics of the invention. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998).

Arthrex has alleged that its FiberWire products do not infringe because the Hunter 446 Patent claims do not expressly mention "coating" and because FiberWire's coating allegedly

[1] For purposes of this motion, Mitek includes Arthrex's TigerWire products within the term "FiberWire." TigerWire is however manufactured slightly differently because it is not dyed, and has a black nylon yarn that replaces one of the PET yarns that are used in FiberWire's construction.

materially affects the novel and basic characteristics of the invention. In support of its position, Arthrex served expert reports from Dr. Norm Gitis and Dr. Debi Mukherjee.

B. Dr. Gitis' Report

Dr. Gitis, who professes that he is an expert in "testing" but admits that he is not an expert "on sutures" (Ex. 1 at 15:14-17), is affiliated with the Center for Tribology, Inc. ("CETR"). In his expert report, he discusses tests carried out at CETR purportedly comparing certain characteristics of two FiberWire samples, one Dr. Gitis termed "coated" and another he termed "uncoated"[2] (Ex. 2). These tests included a so-called "pliability" test, a knot slippage-strength test, a knot tie-down test, a friction test, tissue drag tests, and chatter analyses (*id.*). These tests are hereinafter referred to as "the CETR Tests."[3]

Dr. Gitis' role was limited to conducting the CETR tests and reporting the results. He did not analyze the technical significance of those tests and how they relate to the patent issues in the case:

> Q. Have you been asked to provide opinions, or have you just performed certain tests and provide the test results?
> A. Not – I have not been asked to provide opinions, only to test and to produce test results.

(Ex. 1 at 12:2-7; 62:1-3; 63:7-13; 312:6-11). As Dr. Gitis admitted, even if wanted to, he could not testify as to whether the coating on FiberWire caused a difference in suture properties because he did not know how the "coated" and "uncoated" samples were constructed or

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[2] Mitek does not agree that the only difference between the "coated" and "uncoated" sutures is the presence or absence of coating, but, for the purpose of this motion, uses the "coated" and "uncoated" nomenclature for the tested samples.

[3] For the record, Mitek does not necessarily agree that any of these tests, even if valid and admissible, are relevant to the issue of whether FiberWire's coating materially affects the basic and novel properties, which the Court has construed as including, *inter alia*, "not significantly sacrificing the physical properties *of the constituent elements* of the suture" (emphasis added). Mitek does not press this argument for the purpose of this motion, however.

manufactured, and this information was necessary to form a causation opinion (*id.* at 93:15-94:20; 221:1-226:6).

The bottom line is that Dr. Gitis' report concerning the CETR tests merely provides numerical results of testing. As one example, Dr. Gitis reports in Table 3 of his report that the "run down force" for coated suture is 0.22 ± 0.05 kg vs. 0.40 ± 0.14 kg for uncoated suture, and Dr. Gitis concludes from this that "the coated sutures had lower run down force when compared to the uncoated sutures" (Ex. 2 at 8-9). Dr. Gitis' report also concludes that this difference is "statistically significant" (*id.* at 16-17). Dr. Gitis offers no opinion as to whether the difference between a run down force of 0.22 ± 0.05 kg and 0.40 ± 0.14 kg – whether statistically significant or not – has any real life meaning. *i.e.*, whether one skilled in the art would understand that difference to constitute a *material effect* on the basic and novel properties of the 446 Hunter Patent invention.[4]

C. Dr. Mukherjee's Report

Apparently recognizing that evidence tying the CETR test results to the issues in this case would be needed, Arthrex submitted Dr. Mukherjee's expert report. Dr. Mukherjee is an associate professor at Louisiana State University (Ex. 4 at 13:22-14:1).

Dr. Mukherjee states in his expert report that Dr. Gitis' tests "conclusively show that the knot tie-down, chatter, coefficient of friction, knot security, pliability and tissue drag characteristics of FiberWire are each *materially affected* by the addition of coating" (Ex. 5 at 25, emphasis added). The problem is, Dr. Mukherjee, by his own admission, is not an expert in suture testing (Ex. 4 at 387:16-17). He was not physically present and did not witness any of

[4] This is in contrast to testimony of Arthrex expert, Dr. Burks, a surgeon who testified to his own, personal analysis of FiberWire sutures and concluded that the difference between "coated" and "uncoated" sutures was merely "subtle" (Ex. 3 at 87:7-13; 96:6-19; 97:19-25). Dr. Burks also testified that handleability features of FiberWire were "good," but that what distinguishes FiberWire for him is primarily its strength (*id.* at 46:5-11).

Dr. Gitis' tests (*id.* at 36:16-18). Further, he admitted at his deposition that he is "not really" an expert "in explaining the results of this data that Dr. Gitis did and how it relates to FiberWire's coating" (*id.* at 452:16-19). And he admitted that he did no analysis of any of the CETR data to see how it compares to sutures in general so he could determine whether any of the alleged effects of coating on the FiberWire were material (*id.* at 454:3-7).

Indeed, as the deposition excerpts provided below reveal, for each of the six CETR tests in the Gitis report, Dr. Mukherjee admitted either that he was not familiar with the test procedures used by CETR, or that he did not really have an opinion as to whether the coating had an effect on the tested , *or both*:

With respect to the CETR Knot Slippage Strength Test:

> Q. And the tests before that, the knot slippage test, were you – are you familiar with how those tests were done?
>
> A. No.

(*id.* at 450:6-9).

> Q. [B]ased on the testing that's reported in table 2, do you have an opinion whether the – the coating on FiberWire caused the knot strength to either increase or decrease as reported in table 2?
>
> A. Again, I have to look at the statistical analysis of these data. And again, Norm will – will tell you that. And I'm not – I am not really sure that I can answer your question. I cannot.

(*id.* at 449:13-21).

With respect to the CETR Knot Run Down Test:

> Q. Next test is the knot rundown test. … Are you familiar with how this test was performed?
>
> A. Not really. He's the expert. Norm Gitis is expert. He did what is procedure he used.

(*id.* at 449:22-450:5).

Q. Do you have an opinion as to whether the FiberWire's coating affects the knot rundown --

Objection vague.

Q. -- based on table 3?

A. No, I do not.

(*id.* at 450:16-21).

With respect to the CETR Friction Test:

Q. The next test is a friction test. Are you familiar with how that test was performed?

A. Again, Norm is the expert. That's what he did. I do not know.

(*id.* at 451:13-16).

Q. Are you an expert in explaining the results of this data that Dr. Gitis did and how it relates to FiberWire's coating?

A. Not really.

(*id.* at 452:16-19).

With respect to the CETR chatter test:

Q. The chatter data on page 11 of the CETR report … Do you know how that data was determined?

A. No. Again, Norm Gitis the person who answer the question.

(*id.* at 454:8-13).

Q. [S]o do you have any opinions about how the coating affects the chatter of a suture, of the FiberWire suture?

A. The answer is no.

(*id.* at 456:11-14).

With respect to the CETR tissue drag test:

Q. Next test is a tissue drag test. Do you know how that test was performed?

A. No.

(*id.* at 456:15-17)

Q. Do you have any opinions about how the coating on FiberWire affects the drag force?

A. No.

(*id.* at 457:15-17).

With respect to the CETR pliability test:

Q. Okay, do you see on page 2 of his report, it refers to pliability tests at the bottom?

A. Yeah.

Q. Okay. And are you familiar with the pliability tests that he did?

A. Vaguely, because he's expert. He decided what tests to be done. We need this kind of data. So, he said we need this. So that's the discussion I had with – I had with him several times, but the actual procedure, he's the expert.

Q. He's the expert on that?

A. Yeah.

Q. Okay. Do you know what procedure he used?

A. It's in the drawing there, but I haven't – you know, myself, I didn't do it.

…

Q. Did you approve the pliability tests that Dr. Gitis did before he did it?

Objection, vague.

A. He's the authority. He decided on it and – and we just did the – we didn't measure pliability, all right? That is the extent of conversation I had. He decided the procedure and the technique.

(*id.* at 383:11-25; 425:2-9).

II. ARGUMENT

Because Dr. Mukherjee has no basis for opining on the meaning of the CETR test results – and, indeed, has denied even having opinions on how FiberWire's coating affects the properties tested in the CETR reports -- he should not be permitted to offer any testimony about those test results. Particularly, he should not be permitted to testify whether or not the CETR test results evidence that coating on FiberWire has a material effect on the basic and novel properties on the invention of the Hunter 446 Patent. And because Arthrex has no way to tie the CETR test results to the issues in this case, the CETR test results themselves should be excluded from evidence because their potential relevance is greatly outweighed by the prejudice attendant to their admission.

A. Dr. Mukherjee's "Opinions" Regarding the CETR Tests Should Be Excluded under FED. R. EVID 702

1. The Rule 702 Gatekeeping Function

Federal Rule of Evidence 702 allows an expert witness to testify "if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." As the proponent of Dr. Mukherjee's testimony, Arthrex bears the burden of establishing, by a preponderance of the evidence, that his testimony is admissible. *United States of America v. Monteiro*, 407 F. Supp. 2d 351, 357 (D. Mass. 2002).

The trial court must perform a gatekeeping function to determine whether the expert is qualified and whether the expert's testimony is sufficiently reliable and "relevant to the task at hand." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). The trial court accomplishes this goal through a preliminary determination that the proffered "technical,

scientific, or other specialized knowledge" evidence is both reliable and relevant under FED. R. EVID. 104(a). FED. R. EVID. 104 advisory committee's note; *Daubert*, 509 U.S. at 589-95.

Federal Rule of Evidence 702 "requires a valid . . . connection to the pertinent inquiry as a precondition to admissibility." *Kuhmo Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999) (quoting *Daubert*, 509 U.S. at 592); *Ruiz-Troche v. Pepsi Cola*, 161 F.3d 77, 81 (1st Cir 1998). This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether the reasoning or methodology properly can be applied to the facts in issue. *Daubert*, 509 U.S. at 592-593; *Monteiro*, 407 F. Supp. 2d at 356. Further, the expert must be qualified to render the opinion. *Sutera v. Perrier Group of America, Inc*., 986 F. Supp. 655, 660 (D. Mass. 1997).

2. Dr. Mukherjee Admitted His Lack of Expertise to Offer "Opinions" Regarding the CETR Testing, and His Opinions Lack Reliability

Dr. Mukherjee should not be permitted to testify about the CETR test results because, despite the "opinion" expressed in the expert report bearing his name -- but apparently largely written by Arthrex's attorneys (Ex. 4 at 126:20-129:7 (referencing Dr. Mukherjee's Responsive Expert Report, Exhibit 239 to his deposition)) -- he has admitted that *he has no opinion* on how the coating on FiberWire affected most of the tested properties of the suture. This is not surprising since he also professed no knowledge of the CETR tests and how they were carried out. He has also admitted that he does not have the expertise to explain how the CETR test results relate to the effects of FiberWire's coating:

Q. Are you an expert in explaining the results of this data that Dr. Gitis did and how it relates to FiberWire's coating?
A. Not really.

(*id.* at 452:16-19).

Even if Dr. Mukherjee were to have a post-deposition revelation and decide, contrary to his deposition testimony, that he does indeed have opinions on the effects of FiberWire's coating, his waivering testimony, his admissions of his lack of expertise to construe the test results and his lack of knowledge about the tests themselves would unambiguously demonstrate that his opinions do not meet the reliability standard for admission as set forth in FED. R. EVID 702. Any such opinion testimony would not be based on sufficient facts, and would not be the product of reliable principles and methods or reliable application of those principles and methods. Further, Dr. Mukherjee bluntly admitted his lack of expertise to explain the results of the CETR data and how it relates to FiberWire's coating.

It would appear that Arthrex would like to give the CETR tests the imprimatur of validity and weightiness by having Dr. Mukherjee testify about them, even though he claims no expertise with respect to interpreting them. If he were allowed to testify about the CETR tests, there is too great a risk that, because of his education and experience, the jury would indeed give credence to his opinions when they deserve no credence. *United States v. Hines*, 55 F.Supp.2d 62, 64 (D. Mass. 1999) (noting that "a certain patina attaches to an expert's testimony unlike any other witness: this is science, a professional's judgment, the jury may think, and give more credence to the testimony than it may deserve"). For these reasons, any opinions Arthrex might try to offer from Dr. Mukherjee relating to the CETR tests should be excluded.

III. THE CETR TESTS THEMSELVES SHOULD BE EXCLUDED UNDER FED. R. EVID 403

The issue for the jury to decide is not whether the coating on FiberWire has "any" affect on any property of the suture, but whether it has a *material effect* on the basic and novel properties of the invention of the Hunter 446 Patent, as those properties have been defined by the Court. An effect on the basic and novel characteristics of an invention is "material" if the effect is

of importance or of consequence to those of ordinary skill in the art. *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354 (Fed. Cir. 1998). The numerical results in Dr. Gitis' report – or even his opinion that the test results show "statistically significant" differences between the tested properties of coated and uncoated sutures – say nothing about whether any effect of FiberWire's coating is material.

The CETR tests are inadmissible to prove noninfringement under FED. R. EVID 403 because any relevance they might have is substantially outweighed by the danger of unfair prejudice, confusion of the issues, misleading the jury, and waste of time. As explained above, Dr. Mukherjee cannot offer an opinion on whether FiberWire's coating affects its properties. Dr. Gitis was only asked to produce test results, not form opinions, and therefore reached no opinion with respect to how the CETR test results relate to the patent issues in the case. Thus, Arthrex has not proffered a witness who can testify on causation – *i.e.*, that any differences in suture properties revealed by CETR tests are due to coating, and not any other differences between the samples. And Arthrex has not proffered a witness who can testify that any differences meet the materiality standard. Without such testimony, the jury will have no valid method for determining what difference, if any, in Arthrex's test results can be attributed to FiberWire's coating (as opposed to other differences between the tested samples) and whether those differences meet the "materiality" standard. Without such testimony, the CETR tests have no relation to the patent issues in this case and are therefore irrelevant. Without such testimony, there is a substantial danger that the jury will be confused or misled by the data. The substantial likelihood of prejudice from admission of the CETR tests significantly outweighs their lack of relevance, and they should be excluded under FED. R. EVID 403.

IV. CONCLUSION

For the foregoing reasons, Defendants should be precluded from admitting evidence or argument relating to the CETR pliability, knot slippage-strength, knot tie-down, friction, tissue drag, and chatter tests.

Dated: July 13, 2007

DEPUY MITEK, INC.,
By its attorneys,

/s/ Michael J. Bonella

Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
WOODCOCK WASHBURN LLP
Cira Centre, 12th Floor
2929 Arch Street
Philadelphia, PA 19104
(215) 568-3100

Daniel J. Gleason (BBO #194900)
Heather Repicky (BBO #663347)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604
617-439-2000

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

Plaintiff DePuy Mitek's Motion *In Limine* (No. 1) To Exclude Evidence Regarding CETR Testing; and

Plaintiff DePuy Mitek's Memorandum in Support of its Motion *In Limine* (No. 1) To Exclude Evidence Regarding CETR Testing

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro LLP
1825 Eye Street, NW
Washington, DC 20006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: July 13, 2007

/s/ Erich M. Falke
Erich M. Falke

EXHIBIT 1

IN THE UNITED STATES DISTRICT COURT FOR THE

DISTRICT OF MASSACHUSETTS

DEPUY MITEK INC., a Massachusetts Corporation,	:	
Plaintiff,	:	
vs.	:	Civil Action No.
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom,	:	04-12457
Defendants.	:	

Washington, D.C.

Wednesday, June 21, 2006

Videotape Deposition of:

DR. NORM GITIS,

The witness, was called for examination by counsel for the Plaintiff, pursuant to notice, commencing at 8:15 a.m., at the law offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, D.C., before Dawn A. Jaques, Certified Shorthand Reporter and Notary Public in and for the District of Columbia, when were present on behalf of the respective parties:

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Dr. Mukherjee, Dr. Burks, and/or Dickstein Shapiro Morin & Oshinsky concerning the lawsuit.
Have you produced those?
A. Yes, I did.
Q. Do you have invoices that you've charged in this matter, any bills that you've sent to someone?
A. I do have invoices, but I did not bring them. I did not produce them.
Q. Okay. And who did you send those to, to the law firm or Anthrex?
A. To the law firm.
Q. Request No. 5 is all documents and things concerning this lawsuit. Have you produced all the documents and things that you have concerning this lawsuit?
A. Yes.
Q. Turn to the next page, Things To Be Produced says, Request No. 1, all tested and untested samples referred to in the Comparative Suture Testing. Do you see that?
A. Yes.
Q. Have you produced all the FiberWire samples that remain from the testing that you did?
A. Yes.

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Q. So you have no more FiberWire samples in your possession?
A. None.
Q. None? Did you give any to counsel within the last week or two?
A. Several weeks ago, but not necessarily within the last week.
Q. So just to confirm, you produced samples to us. Is there no other samples?
MR. TAMBURO: Nothing else.
(DePuy Mitek Exhibit No. 381 was marked for identification.)
BY MR. BONELLA:
Q. Next I'll show you DuPuy Mitek Exhibit 381. It's entitled "Comparative Suture Testing" from CETR. I'll ask you if you recognize DePuy Mitek Exhibit 381?
A. Yes, I do.
Q. And what is DePuy Mitek Exhibit 381?
A. Our test report on the comparative suture testing.
Q. Are you hired as an expert in this case? Are you being asked to serve as an expert?
A. I've been asked to produce -- to test and to produce a test report. Whether you call it

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expert or not, I don't --
Q. Have you been asked to provide opinions, or have you just been asked to perform certain tests and provide the test results?
A. Not -- I have not been asked to provide any opinions, only to test and to produce test results.
(DePuy Mitek Exhibit No. 382 was marked for identification.)
BY MR. BONELLA:
Q. Next I'd like to show you DePuy Mitek Exhibit 382. It's Bates numbers CETR 76 through 79. It's four pages. I ask you if you recognize Exhibit 382?
A. Yes, I do.
Q. What is DePuy Mitek Exhibit 382?
A. These are additional data plots to the earlier produced test report.
Q. Is this another report that you provided?
A. It's not a new report. It's just -- what happened with the original test report, we produced all the data in the table, but only typical data in the data plot, and my understanding was that we have been requested to

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provide all the data plots, so these additional data are just the entire data plots of all the test data generated at Center For Tribology.
Q. DePuy Mitek Exhibit 382, did you sign anything that says it's part of your report, or have you signed something saying it's a supplement to your report?
A. No, I did not. I just provided this data without signature, sorry.
Q. Okay. So in front of you is DePuy Mitek Exhibit 381 and 382. Do DePuy Mitek Exhibits 381 and 382 detail all the work that you've done in this case?
A. Yes.
Q. And do they contain all the facts and things that you expect to testify about?
A. Yes, they do.
Q. Is there anything you expect to testify about that's not in DePuy Mitek Exhibit 381 and 382?
A. No.
Q. Have you been asked to prepare any more reports or to provide any supplements or changes to Exhibits 381 and 382?
A. Not as far as I know.

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Q. Okay. Are you anticipating making any changes or supplements to Exhibits 381 and 382?
A. Not unless I am asked.
Q. Do Exhibits 381 and 382 contain a listing of all the materials that you considered in forming the reports?
A. Yes.
(DePuy Mitek Exhibit No. 383 was marked for identification.)
BY MR. BONELLA:
Q. I'd like to show you DePuy Mitek Exhibit 383. It was produced just this morning. It's Bates number CETR 86 through 91.
I ask you if you recognize this as an e-mail string that you were a part of?
A. Yes.
Q. Okay. If you could turn to -- I only have one copy this -- the second page, CETR 87. There's an e-mail from you to Mr. Tamburo. Do you see that?
A. Yes.
Q. And you say, "Dear Sal, I have sent you the FedEx copies and sterilization procedures.
"Within the next few days (after either Michael or Vishal come back to work from their

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business trips), we will send you all the raw data from our lab computer.
"Again, if you want, we can FedEx either you or your expert the pile of tested suture pieces to separate coated and uncoated ones, since we did not keep them separately and cannot distinguish them now (we are experts on testing, not on sutures)." Do you see that?
A. Yes.
Q. And that's an e-mail from you to Mr. Tamburo on April 13th, 2006?
A. Yes.
Q. That last part says we are experts on testing, not on sutures. Do you agree with that statement, that you're an expert on testing, not on sutures?
A. Yes, I do.
Q. And why do you agree with that?
A. The last 30 years of my life I spent on tribology and mechanical testing of materials and not on investigation of suture design or suture technology or suture applications.
Q. Did you read Dr. Mukherjee's expert reports?
A. Yes, I did.

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Q. When did you do that?
A. I'm sorry, I'm sorry, taking back. No, I did not read. I read his deposition, but I did not read his expert report.
Q. Okay. How about Dr. Hermes, have you read an expert report from a Dr. Hermes, any expert reports from Dr. Hermes?
A. No, I did not.
Q. How about Dr. David Brookstein, have you read any of his expert reports?
A. I read something. I don't remember whether it was his report or his rebuttal, something where he dedicated several pages describing our test report.
Q. Okay. And how about expert reports from a Mr. Witherspoon, have you seen any of those?
A. No, I have not.
Q. And how about expert reports from Dr. Burks, have you seen any of those?
A. No, I have not.
Q. If you could turn to Exhibit 381, that's the Comparative Suture Testing report. Turn to page -- this doesn't have a page number. It's your c.v., Appendix 2a.
A. Yes.

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Q. I'd like to ask you about your education.
A. Yes.
Q. You have an M.S., Master's of Science, in Mechanical Engineering from 1978 from the USSR, Polytech University?
A. Yes.
Q. M.S., is that Master's of Science?
A. Yes.
Q. Do you have a Bachelor's of Science degree?
A. Yes, I do, but in the former USSR, they did not separate -- it was a bachelor. If you have a five-year program to get master's, you kind of skip bachelor, so it was a program to get master's degree right away.
Q. Okay. And then you obtained a Ph.D. in Mechanical Engineering and Tribology in 1983 from the USSR Academy of Sciences; is that correct?
A. Yes.
Q. Where is the USSR Polytech University?
A. City of Odessa, Ukraine.
Q. And how about the USSR Academy of Sciences, where is that?
A. City of Moscow, Russia.

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Q. Okay. So you have no opinions about the patent that's involved in this case?
A. No, I do not.
Q. The project goal it says -- is that the description of what you were asked to do?
A. Yes, pretty much.
Q. Were you asked to do anything other than what's stated in the project goal?
A. It's stated as performing comparative mechanical and tribological testing of two types of Fiberwire. Yes, nothing else has been asked me to do.
Q. That was nothing else --
A. Nothing else has been asked.
Q. Okay. Are you experienced in doing tensile tests?
A. Yes.
Q. Okay. Have you done tensile testing on sutures before this case?
A. Yes.
Q. Okay. Have you done tensile tests on other textiles before this case?
A. I don't remember.
Q. In the other expert testing that you've done, did you do any testing on -- did you do any

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expert opinions on patents?
A. Yes, I did.
Q. You did? Okay. Is that infringement?
A. Yes.
Q. How about validity?
A. Yes.
Q. But you weren't asked to do that in this case?
A. That's correct. I was specifically told that there is an expert witness, Dr. Mukhergee, who will provide opinions on the patent, and I would be -- my role would be only to do testing and to present the test report.
Q. Tribology is the study that deals with design friction wear and lubrication of interacting surfaces and relative motion; is that right?
A. Yes.
Q. Okay. Do you recall -- I think you said no, but just to check, you don't recall the relative numbers and the data that you obtained for any of the tests you did for Ethicon and U.S. Surgical?
A. I am very sorry, I don't remember that.
Q. Going back to your report, Exhibit 381,

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in the first page, second paragraph, you said 90 percent of CETR revenue is from design and sales of equipment; is that right?
A. Yes.
Q. And 10 percent is from testing/consulting services, right?
A. Yes.
Q. And then you say that you've done -- you supplied equipment to Ethicon, right?
A. Yes.
Q. Do you know what percentage of revenue that was generated from Ethicon was for equipment as opposed to testing/consulting services?
A. For Ethicon?
Q. Yeah.
MR. TAMBURO: Objection, vague. You mean his revenue?
MR. BONELLA: CETR's revenue.
THE WITNESS: I'm confused, yeah.
BY MR. BONELLA:
Q. The revenue that CETR has generated from Ethicon, what percentage was from equipment sales to Ethicon, what percentage was for consulting services?
A. I don't remember the exact numbers, but

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they're obviously in our database, easy to obtain, but my wild guess is very close to our average numbers, 90 percent from equipment sales and 10 or less percent from testing.
Q. Okay. In your report you say that you're charging $2,500 per day and $10,000 per week for regular lab testing services, and double prices for priority?
A. That's correct.
Q. In this case, did you charge the priority?
A. For Ethicon?
Q. No, no, for your work in this case.
A. Partly, yes.
Q. Partly, yes?
A. Yes.
Q. For the testing, did you charge the priority?
A. Yeah, only for the testing.
Q. Okay. But not for the report?
A. Not for the rest of the report -- of the work, no.
Q. Okay. And you say $2,500 per day is what you're charging?
A. Actually, when we did the work for

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answered.
THE WITNESS: I assume that they actually use what they describe in their published papers.
BY MR. BONELLA:
Q. You didn't read all their published papers, did you, from Ethicon?
A. I don't have time to read all their published papers. Hopefully they publish many papers, but I am just familiar with the papers that happen to come to my attention.
Q. Method 2, you say in the document -- you reference an ASTM Standard D747.
A. Yes.
Q. And you say it's a standard test method for apparent bending modulus of plastics by means of a cantilever beam. Do you see that?
A. It's not that I said, it's just how -- it's name of the standard, yeah.
Q. Right. And it says -- you say in this document widely used in the textile industry?
A. Yes.
Q. Okay. Any other reason why you chose Method 1 over Method 2?
A. I believe that the only reason, or at

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least the main reason, was trying to stick to the methodology used by Ethicon.
Q. Okay.
A. And I am sorry, we have two references here to their paper as well as to their patent, but I already mentioned it.
Q. Okay. Do you agree that the ASTM D747 is widely used in the textile industry?
A. To the best of my knowledge, yes.
Q. Okay. Is the Method 1 widely used in the textile industry for pliability and bendability?
A. I cannot tell for the textile industry.
Q. Okay. Have you ever used the Method 1 procedure for determining pliability or bendability before the tests you did in this case?
A. Our engineer, Michael, had a strong memory, a strong recollection, that this is what Ethicon did on our tester. Personally, I didn't have this recollection, but he had.
Q. Okay. Any other times that you used Method 1 for testing pliability/bendability?
A. No.
Q. Okay. So you don't actually know whether you used Method 1 when you did the test

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for Ethicon?
A. Can you repeat your question?
Q. You said Michael remembered -- thought he remembered.
A. He had strong feelings that he remembered exactly.
Q. But you yourself don't actually know whether Method 1 was used on the Ethicon testing?
A. By us?
Q. No, by you. Do you know personally whether Method 1 was used on the Ethicon testing?
A. It was described in their patent and in their papers, so I know.
Q. I'm sorry. No, no, I'm asking a different question. The testing that CETR did for Ethicon --
A. I don't remember.
Q. Did anyone discuss whether Method 1 or Method 2 should be used besides yourself and Mr. Vinogradov and Mr. Khosla? In other words, did you discuss with Dr. Mukherjee or the lawyers?
A. I do not remember whether we discussed specifically choices of one or two, but we kind of in general discussed these procedures, and most likely we in general discussed best one.

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Q. You said most likely. I'd like to know whether you actually remember discussing Method 1 versus Method 2 with either the lawyers or Dr. Mukhergee?
A. I don't remember discussing it in particular.
Q. Okay. Do you remember saying anything to either Dr. Mukherjee or the lawyers asking whether they thought Method 1 should be used or Method 2?
A. I am sure that they did not specify because I remember it was my decision, as I said, based on my feelings of we better stick to what Ethicon does.
Q. The samples that you tested, do you know how they were made?
A. No, I do not.
Q. Did you ever see a video showing how FiberWire samples are made?
A. No.
Q. Did you ever see -- did you ever visit the Pearsalls plant?
A. No.
Q. Did you do any analysis to determine the structure of the FiberWire samples?

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A. The only knowledge of structure -- or knowledge, if it may be called structure or not, was taken SEM photos of the fibers.
Q. Okay. Did you do any analysis to determine how the samples were manufactured?
A. No, I did not.
Q. Okay. Did you review any documents that describe how the samples were manufactured?
A. I reviewed deposition of Dr. Mukherjee, and it was -- part of it was somewhere related to production, but I didn't pay much attention.
Q. Anything else you reviewed that had anything to do with manufacturing the FiberWire samples?
A. No.
Q. Now, the samples, the FiberWire samples were sent to you by Dickstein Shapiro?
A. Yes.
Q. And that's the law firm, right?
A. Yes.
Q. Okay. When the samples came to you, in what form were they in?
A. Sutures were on the spools, and both spools were in plastic bags inside a FedEx envelope.

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Q. Okay. And the coated sample was on one spool, and the uncoated was on another spool?
A. Yes.
Q. Were the spools labeled at all?
A. Yes.
Q. Were they -- one said coated, one said uncoated on it?
A. Yes, very clearly.
Q. Okay. I think my question became unclear. I'm going to ask it again.
So were the spools that you received from the law firm, one said coated on it; is that right?
A. Yes.
Q. And the other spool that you received from the law firm said uncoated on it?
A. I am sorry, I don't remember whether it said uncoated, but I remember that there was no doubt whatsoever to distinguish that one was coated, one was not, but I don't remember wording specifically on the label.
The spools have labels, and I don't remember wording on the labels.
Q. So the two spools you received from the law firm had labels that conveyed to you that one

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of the spools had coated FiberWire and the other spool had uncoated FiberWire?
A. Yes.
Q. Where are the spools?
A. My apologies, somehow we lost them.
Q. You lost them, okay.
A. Yeah, unless -- either we lost them or we sent them, the samples, to the expert witness, but somehow they disappeared from our lab.
Q. Okay. So at one point you had the samples. Then did you -- you used some of the sample for testing, right, for your own CETR testing, right?
A. Yes.
Q. And you sent some samples to a Dr. Burks?
A. Yes.
Q. And the samples that you sent to Dr. Burks, were they on spools?
A. I do not remember at this second.
Q. Did you send samples to Dr. Mukherjee?
A. We did send samples to him, yes.
Q. What samples did you send to him?
A. Same thing, of coated and uncoated. And I don't remember, maybe one of the shipments was

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on the spools. I don't remember.
Q. Do you have any spools of your own that you put sample on?
A. No.
Q. So if you did send spools, they were the spools that you received?
A. On the original spools. We don't have any other spools in the building.
Q. So if you did send spools to a witness, they were on the spools that you received?
A. Correct.
Q. Okay. When you sent the samples to Dr. Burks, do you recall doing anything with those samples?
MR. TAMBURO: Objection, vague.
THE WITNESS: I do not.
BY MR. BONELLA:
Q. Do you recall like labeling them or segregating them in any way?
A. What happened personally, I was not involved in sending samples to either expert. They were sent by my engineer, my secretary, and so I -- this is why I am a little bit unclear whether they were sent on the spools or not.
Q. Do you remember doing anything to the

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A It indicates untie, yeah.
Q So that sample untied?
A Yes.
Q So for any sample that untied, you would have that vertical line; is that right?
A Yes.
Q So only one sample?
A Maybe only one of them untied.
Q Okay. Now, if we go to the knot strength and knot failure data that you presented in the table --
A Yes.
Q -- you have the coated and uncoated knot strength and knot failure, right?
A Yes.
Q See how the coated sample number 1, knot strength and knot failure was 3.06. See that?
A Yes.
Q And No. 3, coated was 3.15. Do you see that?
A Yes.
Q And sample 3, uncoated was 2.42. Do you see that?
A Yes.
Q And sample 4, uncoated was 2.98. Do you

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see that?
A Yes.
Q So 25 percent of the time, the coated suture had a knot strength and knot failure that was greater than the uncoated.
A You want to say that 75 percent of the time uncoated had higher than coated.
Q That's not my question. My question was 25 percent of the time, coated had a knot strength and knot failure that was greater than the uncoated?
A If you want to count, let me count. You already counted you're saying. So you counted -- what do you call 25 percent of the time? You understand that samples are completely independent.
Q Right. So sample 1 coated has nothing to do with sample 1 uncoated?
A Right, completely different, yeah.
Q I'm saying two of the coated values at knot strength, at knot failure, were greater than two of the uncoated values?
A Yes.
Q Why was that?
A We already discussed it when we

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discussed the pliability test data, that manufacturing of sutures doesn't -- manufacturing of any polymers and manufacturing of any textiles cannot produce completely ideally uniform samples and materials. They all are slightly different, so these are the nature of fluctuations in the materials, and so this is the reason why we had to test multiple samples.
Q If you tested two more and it came out that way, then you would have four, right, that were different, right?
A Right.
Q So how can you conclude -- can you conclude anything just based on this test where two of the eight were --
A This is why when we made the draft of the report and showed it to the law firm and expert witness, he said he needs statistical analysis, so we did statistical analysis.
At the end of this report, we have statistical analysis which shows that, statistically, results of Table 2, slippage strength, results of Table 2 are three times better than the minimum statistically correct data required.

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Q We'll get to statistics, but just cause and effect. Can you necessarily just conclude from this data, knot strength and knot failure, that the -- are you qualified to draw a conclusion about the effect of coating on the sutures?
MR. TAMBURO: Objection, vague.
THE WITNESS: I prefer to make conclusions only directly -- only on the direct test results. I don't know anything about processes involved in manufacturing sutures.
BY MR. BONELLA:
Q So you don't know how each suture, the coated and uncoated, were actually made, correct?
A That's correct.
Q So you don't necessarily know whether the differences in the results are necessarily attributable to coating?
MR. TAMBURO: Calls for speculation.
THE WITNESS: I only know that two groups of sutures, one called coated, one called uncoated, with very clear labels on them, produced different results, but I don't know whether, in addition to coatings, they had hundred more variables.
BY MR. BONELLA:

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Q So you can't necessarily draw conclusions based on the data that you generated?
A No, just opposite. I can draw very clear conclusions based on my data that the coated group and uncoated group had different average values of knot slippage and knot failure, but I cannot say whether it's related to coating or to some other process.
Q Is that true for all the tests you ran?
A Yes. For all the tests, I can only make conclusions about direct test results. I cannot make conclusions about processes or design of the samples.
Q And you can't draw a conclusion about what causes the difference in the results?
A I only know their names, coated and uncoated. I don't know what is behind.
Q So you can't draw a conclusion about what actually caused the difference in the results?
A That's correct.
Q Is it possible for the data that was generated there was variability in manufacturing that the coated was actually higher than the uncoated due to variables in manufacturing of the

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two samples?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: Pure speculation. I'm not familiar with any aspects of suture manufacturing.
BY MR. BONELLA:
Q But it could be?
MR. TAMBURO: Calls for speculation.
THE WITNESS: I will stick to my previous answer.
BY MR. BONELLA:
Q Well, but if variables in manufacturing could cause the coated to be higher than uncoated for some of the samples at knot failure, couldn't just the opposite be true, that variables in manufacturing could cause the uncoated to be higher?
MR. TAMBURO: Objection, calls for speculation.
THE WITNESS: I will stick to my previous answer. I cannot speculate on manufacturing. I don't know how --
BY MR. BONELLA:
Q Didn't you tell me that the variables in manufacturing could cause -- is what caused the

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two coated samples to have values that were higher than two of the uncoated samples?
A Not exactly. I said that variables in manufacturing either at Anthrex or Pearsalls, or maybe at their supplier side, so I don't know, variables in some step of manufacturing can cause differences from sample to sample.
Q So they could just as easily cause differences in the -- that caused the uncoated to be higher than the coated?
MR. TAMBURO: Same objection.
THE WITNESS: I am saying that label uncoated has higher knot failure load than label coated, but -- and I have a very strong belief that this data is very conclusive, but I do not know anything about reasons for this difference, whether those reasons -- this difference between so-called uncoated and so-called coated is due to the coating, or to the label on them, or to the weather in England. I don't know.
BY MR. BONELLA:
Q But I thought you said -- maybe I misunderstood. I thought you said that the two coated samples at 3.06 and 3.15, the reason they might be higher than two of the uncoated samples

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at knot failure was due to manufacturing. Did you say that or not?
A No, no, I did not. I said that the reason of -- the general reason for data fluctuation is caused either in fluctuations between material properties, or between their processes, or between the -- or in geometry of the samples, or in anything else related to their prehistory, which I have no information of.
Q And those same variables could cause the uncoated to be higher than the coated?
MR. TAMBURO: Same objection, calls for speculation.
THE WITNESS: But this is a pure speculation, which I refuse to answer last time.
BY MR. BONELLA:
Q Well, you speculated the one way that --
A No, I don't speculate any way. I don't care about Anthrex or DePuy Mitek. I don't speculate either way.
I am saying that the differences between samples as fluctuation in data is related to sample's history, to sample's manufacturing process and not to the inherent unrepeatability of this test procedure or this tester or these

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holders or these sensors or whatever, but I cannot speculate what causes the difference between uncoated and coated, because as we discussed, I only know labels, coated and uncoated, so I cannot speculate what causes their differences. Erich, you need a new printer.

(DePuy Mitek Exhibit No. 404 was marked for identification.)

BY MR. BONELLA:

Q I'm going to show you the next exhibit, Exhibit 404, which I believe is the knot strength test data and curves for the uncoated samples. I ask you to verify that.

A Uncoated, yes.

MR. TAMBURO: You want him to look through that 8 inches worth of documents?

BY MR. BONELLA:

Q Do you know? Can you just look at the --

A Yeah, I see it. It's uncoated, yeah.

Q Is that the data for the non-slippage test?

A Yes.

(DePuy Mitek Exhibit No. 405 was marked for identification.)

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BY MR. BONELLA:

Q Is Exhibit 405 the graphs and data for the coated non-slippage test?

A Yes.

Q Okay. Let's take, for example, the coated. Turn to the first part. This is where you were putting the preload on, right? The first part of the data should be where you put the preload on; is that right?

A Yes.

Q Okay. There is, for example, sample 1 we'll use an example, there's five columns, right?

A Yes.

Q First column is F sub X. What is that?

A FX is horizontal force in X direction.

Q Force in X direction. If we're looking at Figure 7, your set-up, which is the X direction?

A X direction is parallel to the paper.

Q Parallel to the paper. That's not specific.

A I'm sorry, what are you looking --

Q Figure 7, your test set-up. That's right, you got it.

A No, you said Figure 7.

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Q Oh, do I have the wrong one? I'm sorry, I have the wrong one. Figure 4.

Okay, so where was the X direction for Figure 4?

A Left-right direction within the plane of the paper.

Q I'm having a hard time understanding because there's two planes to the paper. Well, there's one plane, but there's two directions. There's a --

A I'm sorry, do you see -- how to define X. If you see a force sensor, it has some kind of lengths, so X is along the length of the force sensor.

Q Okay. So would the force X be into the diameter of the brass rod?

A Yes.

Q Next column is F sub Z. What is that?

A It's a vertical force.

Q That's the tension force that you're measuring?

A The tension force.

Q That you measure to get the results?

A Yes.

Q T is time and seconds, right?

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A Yes.

Q Z is what?

A Z is vertical displacement.

Q Okay. So that's what you're looking at to determine slippage?

A Yes.

Q And the last column is F sub F. Do you see that?

A Yes.

Q Is that the force in the Y direction?

A Actually, that's friction coefficient.

Q That's friction coefficient?

A Yeah.

Q In kilograms?

A Okay, I am confused.

Q Weren't you trying to keep the forces in the X direction and the Y direction the same?

A No, FY would say FY. So I'm sorry, I confused. I don't remember. I can find it out and let you know. I don't remember specifically.

Q You don't know what FF is? Look FX and FF columns, if you look at those --

A Yes. They seem to be of certainly equal --

Q Except for this sample they're not.

starts from some level of tensioning. Before motion starts in the tissue drag test, there is no real tensioning of the sutures.
BY MR. BONELLA:
Q I understand that, but have you ever seen tension tests where there's no preload?
A Tension test without pretensioning?
Q Without preload.
A It's very hard to do.
Q You open up a mechanical engineering textbook for college and you look at test -- stress/strain curves for tension tests that are presented, some of those go through zero you think?
MR. TAMBURO: Objection, vague, confusing, calls for speculation.
THE WITNESS: Which zero?
BY MR. BONELLA:
Q If it's stress versus strain, it starts at zero and goes up, no preload.
A For sutures?
Q Just for anything.
A Anything and sutures are two different things, or many different things.
Q Okay.

A If you want to do tension test of a solid metal or ceramic sample, you may or may not need preload, but if you want to do tension test of a suture, you have to have some level of tensioning, otherwise if it's completely slacked, then there's no tension test.
Q Okay. On the first -- on your tissue drag, after the force gets up to about 0.5 in the graph --
A Yes.
Q -- can you consider that a preload, and then go from 0.5 to the point at which suture movement goes?
A I have to think about that. That's a good question. I have to think about it. You caught me at the moment that I'm very tired today at the end of the day.
Q Okay. And all your data that you intend to talk about in this case and all the conclusions that you've drawn are all in your exhibit -- in the two reports that you presented?
A I presented only one report.
Q One report and the supplement.
A And supplement, yeah.
Q Yes?

A Yes.
Q Okay. Other than the tissue drag test with needle, did you do any other tests that weren't reported?
A No, we did not.
Q Were you asked to draw any opinions or conclusions about what caused the difference in the results?
MR. TAMBURO: Objection.
THE WITNESS: I was asked by you today, but I was never asked by Dickstein Shapiro.
MR. BONELLA: I don't have any questions.
MR. TAMBURO: No questions.
THE VIDEOGRAPHER: This deposition concludes at 5:18:10 and consists of four tapes.
(Whereupon, at 5:18 p.m., the taking of the deposition was concluded.)

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

----------x
DEPUY MITEK INC., a Massachusetts Corporation,
Plaintiff,
vs. : Civil Action No. 04-12457
ANTHREX, INC., a Delaware Corporation, and PEARSALLS LIMITED, a Private Limited Company of the United Kingdom,
Defendants.
----------x

ACKNOWLEDGMENT OF DEPONENT

I, DR. NORM V. GITIS, do hereby acknowledge that I have read and examined pages 5 through 312 of the transcript of my deposition taken on Wednesday, June 21, 2006, and that:
(Check appropriate box):
( ) the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.
( ) except for the changes noted in the attached errata sheet, the same is a true, correct and complete transcription of the answers given by me to the questions therein recorded.

DATE SIGNATURE

EXHIBIT 2

CENTER FOR TRIBOLOGY, INC.
1715 Dell Avenue
Campbell, CA 95008 USA
(408) 376-4040 Tel • (408) 376-4050 Fax

"Confidential-Non-Patent-Prosecution Counsel Only"

March 23, 2006

Comparative Suture Testing

1. Introduction

Center for Tribology, Inc., abbreviated CETR, is a privately held California corporation, located in the heart of Silicon Valley in the city of Campbell, county of Santa Clara. It was founded by Dr. Norm Gitis in November 1993 and incorporated in California in October 1994. Its main charter has been helping major corporations and universities all over the world in research, development and failure analysis of materials, coatings and lubricants for the computer peripherals (20% of revenues), semiconductor (20% of revenues), biomedical (15% of revenues) and other industries (20% of revenues), as well as for fundamental academic studies (25% of revenues). A list of its customers is attached in Appendix 1.

CETR is a multi-million-dollars corporation with two lines of business, design & sales of mechanical & tribology test equipment (90% of revenues) and testing & consulting services on mechanical & tribological properties of materials and devices (10% of revenues).

CETR is one of the largest and leading producers of mechanical and tribology testers in the world. In particular, it has supplied them to leading domestic suture manufacturers, such as Ethicon, Inc. of Johnson & Johnson and United States Surgical of Tyco Healthcare, as well as such well-known corporations as Gillette, Guidant, Medtronic, Schick, Procter & Gamble, Unilever, etc.

Dr. Norm Gitis, President of CETR, is a well-known expert on tribology testing with 30 years of experience in friction, wear and fatigue testing of materials and devices. His resume is attached in Appendices 2a – 2c.

CETR has successfully provided highest quality laboratory test data in several lawsuits, including most recently between Alaska Airlines, Boeing, and families of victims of the Alaska flight 261 (related to the reliability of a jack-screw/nut assembly on Boeing airplanes and a plane crash in 2000), between American Airlines, Sabre Travel Network and Western Digital (related to the reliability of computer disk drives used for travel reservations), and between Boston Scientific and US Justice Department (related to the quality of implantable cardiovascular stents). It has been charging $ 2,500 per day or $ 10,000 per week for its regular lab testing services and double prices for priority urgent services.

Dr. Gitis has successfully testified in several depositions, most recently in a lawsuit between Seagate Technology and Cornice, Inc. related to the intellectual property on the mechanical design of portable magnetic disk drives. He has also given successful testimonies at several trials, most recently in lawsuits between Swiss Air, Interactive Flight Technology, Avnet and other parties (related to the reliability of computerized on-demand in-flight video system and a crash of Swiss flight 111) in the court of Arizona and between Iomega and Nomai (related to the reliability of Zip high-density floppy-drives) in the Higher Court of

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United Kingdom, courts of Amsterdam, Dusseldorf, etc. He has been charging $ 350 per hour plus trip expenses for his consulting and expert witnessing services.

2. Project Goal

At the end of February 2006 CETR was requested by a law firm of Dickstein, Shapiro, Morin & Oshinsky, LLP (located at 2101 L Street NW, Washington, DC 20037) and its technical expert Dr. Debi Mukherjee to perform comparative mechanical and tribological testing of two types of FiberWire surgical sutures, coated and uncoated.

They requested the following parameters be tested: i) pliability/bendability, ii) knot tie-down/run-down, iii) knot security, iv) chatter, v) coefficient of friction, vi) tissue drag, vii) microscopy examination.

We have been told that this project is related to a patent infringement lawsuit between DePuy Mitek, a Johnson & Johnson company and Arthrex, the latter being the client of this law firm. Any details of the lawsuit have been neither requested by CETR nor provided to CETR.

3. Suture Samples

In the beginning of March 2006 CETR received via FedEx two new spools of US 2 FiberWire sutures from the law firm, one coated and the other uncoated. Each spool contained approximately 20 m of suture. Two CETR employees Dr. Norm Gitis and Mr. Michael Vinogradov examined the spools of sutures and found them to be apparently brand new.

Upon agreement with the law firm and Dr. Mukherjee, before conducting any tests, we sent both the spools of sutures for ETO sterilization to a reputable sterilization lab Sterile Systems, Division of Medtronic Inc. (located at 520 Watson S.W., Grand Rapids, MI 49504). The same Mr. Michael Vinogradov handled the sutures before the shipment and after receiving them back. Both shipments to and from Sterile Systems were performed via FedEx.

Upon receiving back the sterilized sutures, we handled them only and always with clean-room gloves. We cut about 3 m of each of the coated and uncoated sutures and shipped by FedEx to a surgeon expert, as requested by the law firm. The rest of the spools were utilized in our tests described below.

4. Set Of Test Procedures

Based on the CETR experience with its suture-tester customers Ethicon (New Jersey) and US Surgical (Connecticut), its general expertise in mechanical & tribology testing and familiarity with the relevant literature, as well as on the suggestions of the law firm, CETR has proposed a suit of test procedures for the requested tests, that was approved by the law firm's technical expert Dr. Mukherjee and then performed by CETR in mid-March, 2006.

5. Pliability Tests

The experimental procedure, based on the published work of Rodeheaver et al. [1], was as follows.

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Suture of 50 mm in length and 0.65 mm in diameter was clamped between the force sensor and the lower specimen holder as shown in fig. 1. The suture was preloaded with a tension of 0.5 Kg (5 N). Preloaded suture was then pulled at a force, uniformly increasing at the rate of 0.33 kg/sec. Force and elongation data were continuously monitored and recorded. The strain in the suture was calculated as the ratio of elongation to the initial length of 50 mm. The force-strain plots like the one shown in fig. 2 were made and their slopes were measured. Modulus of elasticity (E) was then calculated by dividing the slope with the cross-sectional area of the suture. Area moment of inertia (I) was calculated assuming a circular cross-sectional area. Stiffness was then calculated as a product of the modulus of elasticity and the area moment of inertia of the suture:

$$K = E*I$$

where
K – Stiffness,
E - Modulus of elasticity - Slope of the force-strain graph / cross-sectional area of the suture

I - Area moment of inertia - $\frac{\pi * D^4}{64}$ where D - diameter of the suture (0.65 mm)

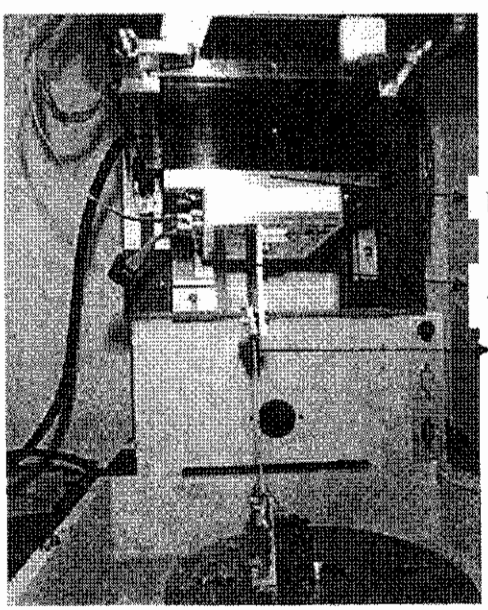

Figure 1. Test set up for pliability testing

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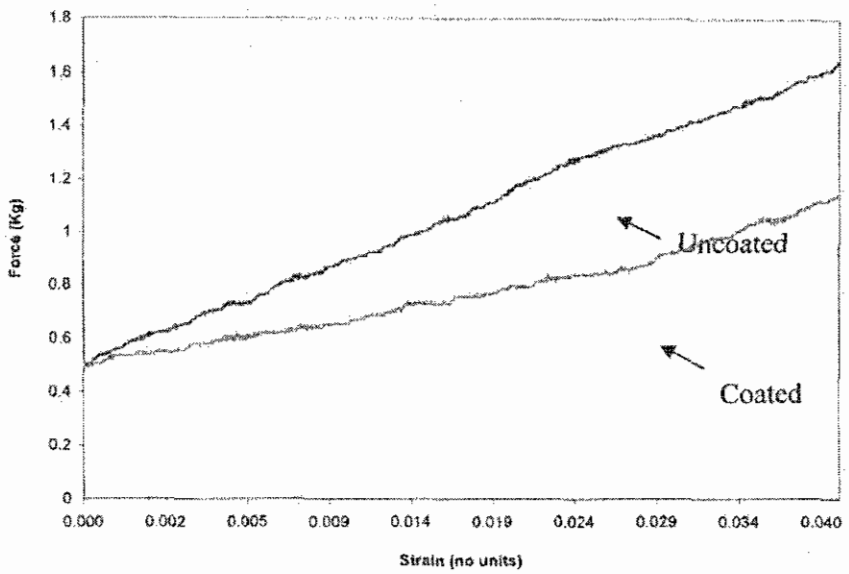

Figure 2. Typical force-strain data for coated and uncoated sutures during pliability tests

The stiffness values as calculated in the above described procedure are summarized in the Table 1.

Table 1. Pliability test data

Exp #	Stiffness (*E10-7 kg x m^2)	
	Coated Suture	Uncoated Suture
1	6.51	10.07
2	7.53	9.73
3	5.98	11.3
4	6.44	11.3
5	4.95	8.29
6	5.67	8.00
7	5.98	9.61
8	5.41	10.6
Average	6.06 ± 1.29	9.93 ± 1.66

The stiffness of the coated sutures was found to be lower than that of the uncoated ones. This suggests that the coated sutures have higher pliability and thus facilitate better handling during surgical use. The test data corresponds well to the data reported by Rodeheaver et al [1].

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6. Knot Slippage Strength Tests

The knot slippage strength tests were conducted to evaluate the knot security offered by each suture. The experimental procedure was carried out based on previous works in the literature [2, 3]. A loop of the suture was formed by tying a 'square knot' as shown in fig 3 [4] around a cylinder of 2.5 cm diameter. The loop thus formed was slipped off the cylinder and soaked in 0.9% weight/volume sodium chloride for 1 minute to closely represent the real environment. The soaked loop was then placed around 2 parallel brass rods of 5 mm diameter, which were mounted onto the UMT-2 machine as shown in fig. 4. A pre-load of 1 N was applied to the loop. The parallel rods were then pulled apart at a constant velocity of 1 mm/sec. The force was continuously monitored and recorded during the experiment. The force when the knot starts slipping was noted as the knot slippage force. The rods continued to be pulled apart until either the knot got untied or a slippage of 3 mm occurred. The force at that instant gives the knot failure force.

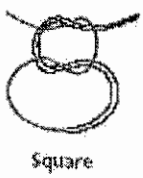

Figure. 3 'Square knot' used for the knot slippage strength tets

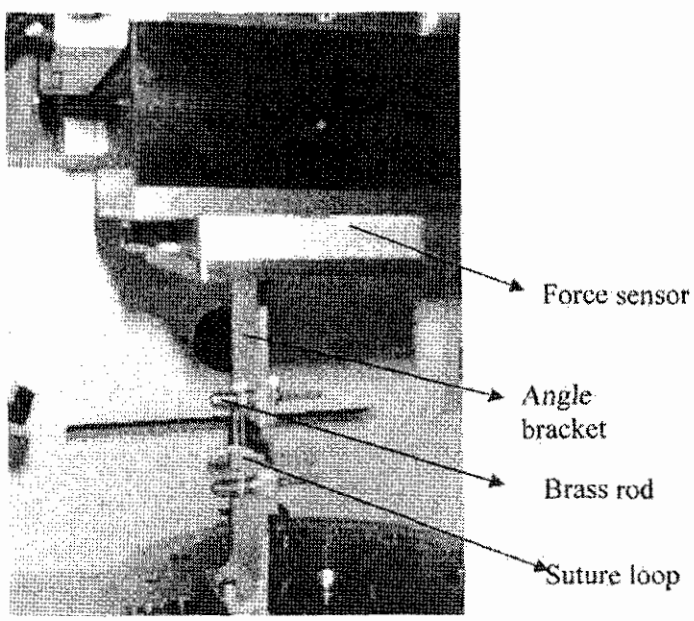

Figure 4. Test set up for knot slippage strength measurement

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The typical force response curves as recorded during the experiments are presented in the fig. 5 below.

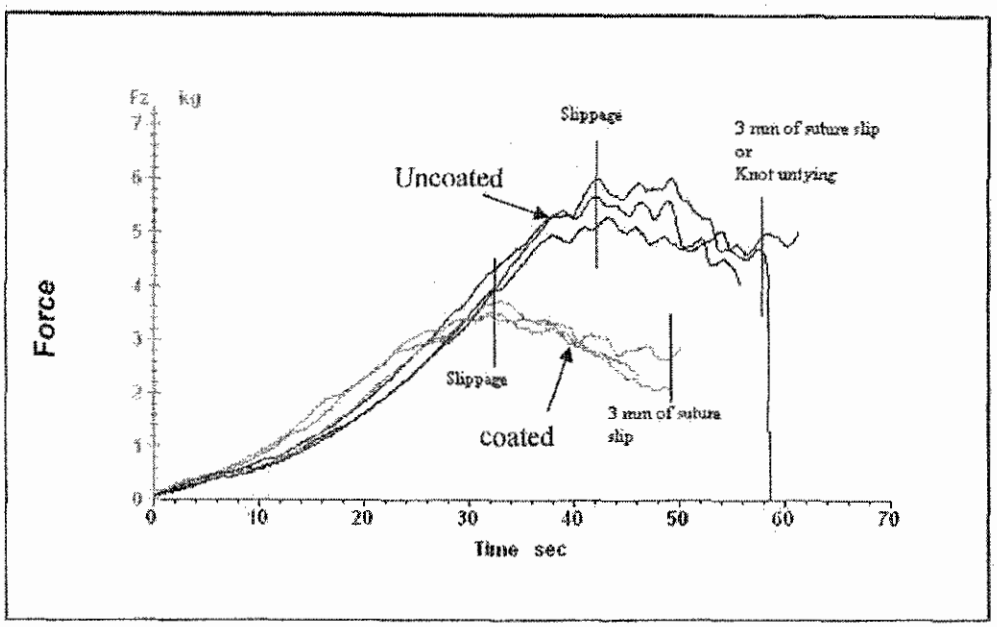

Figure 5. Typical data for force at slippage and knot failure for coated and uncoated sutures

The knot strength values as determined from the curves are summarized in the Table 2 below.

Table 2. Knot strength data for coated and uncoated sutures

Exp #	Knot strength (kg)			
	at slippage		at knot failure	
	Coated	Uncoated	Coated	Uncoated
1	3.52	5.33	3.06	4.09
2	2.36	4.97	2.03	4.09
3	3.46	4.80	3.15	2.42
4	4.25	6.04	2.07	2.98
5	3.74	4.70	2.40	3.53
6	2.43	5.36	2.77	4.79
7	3.47	4.86	2.09	3.45
8	3.27	5.10	2.64	3.90
Average	3.31± 0.95	5.14 ± 0.67	2.52 ± 0.56	3.36 ± 1.19

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From the above data it can be concluded that the knots tied using the coated sutures slipped and failed at lower forces when compared to the knots tied using uncoated sutures. The experimental data compare well with the data reported in the previous works [2, 3].

7. Knot Run-down Tests

The suture was tied with a 'half hitch knot' as shown in fig. 6 [4] around a supplemental cylinder with a 2.5 cm diameter. The loop thus formed was then slipped off the supplemental cylinder and placed on the lower brass rod of the UMT-2 testing machine. The knot was then subjected to running-down by pulling at a constant speed of 1.5 mm/sec on the longer free end in the testing machine as shown in fig. 7. The test procedure was based on the description provided in the literature [5]. The pulling force was continuously recorded as the knot traveled down the suture. Chatter or variation in knot run-down force was also noted.

Figure 6. Half-hitch tied for the knot run-down tests

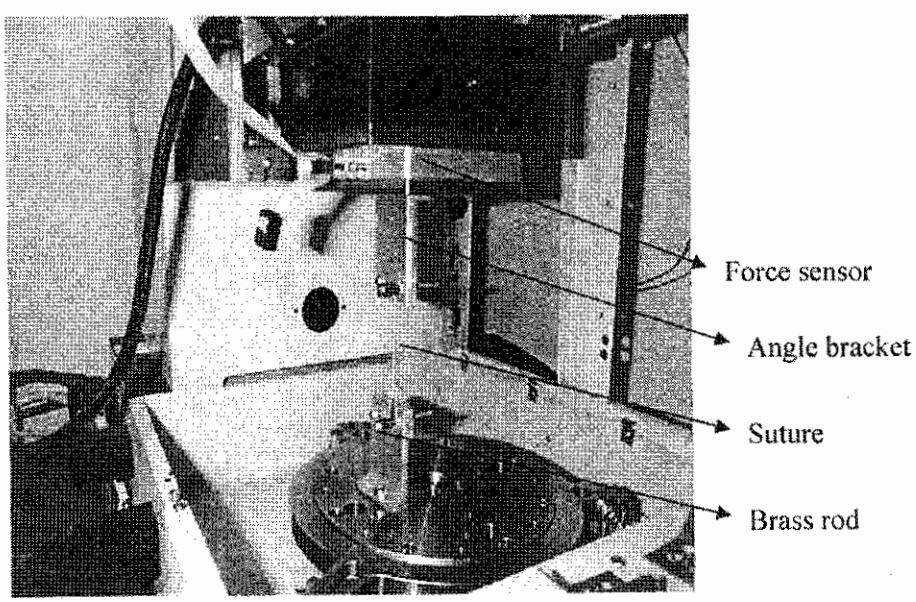

Figure 7. Test set up for the knot run-down test

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The typical pulling force data from the tests performed on coated and uncoated sutures plotted versus time is shown in fig. 8 below:

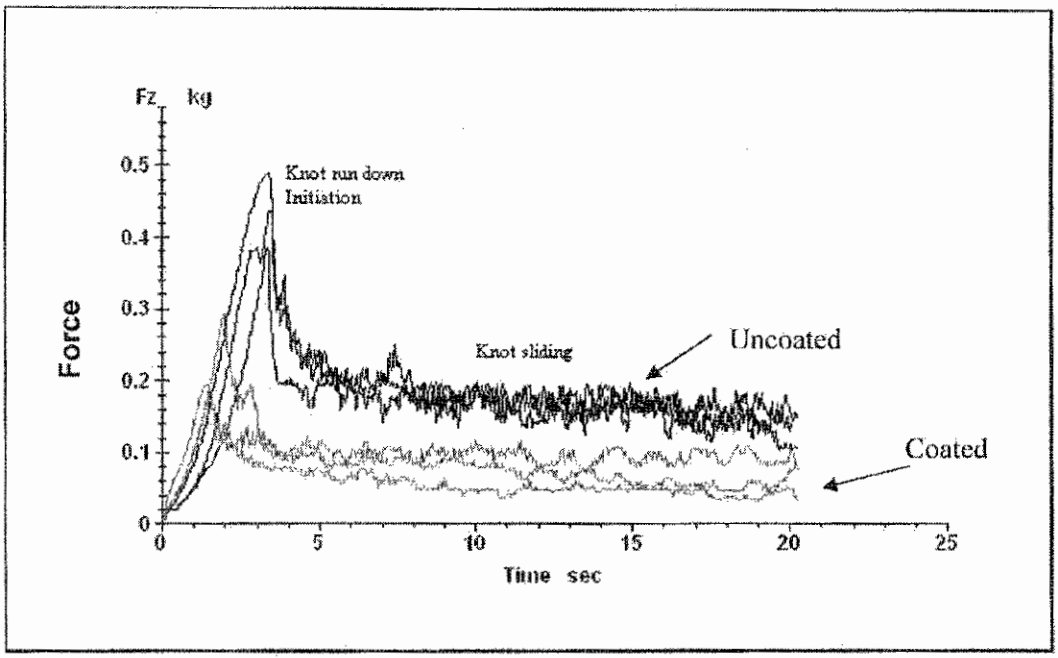

Figure 8. Force versus time for coated and uncoated sutures during knot run-down experiments

The force when the knot begins to slide over the suture was noted from the pulling force data. This gives the run-down force. The run-down force values as measured from the test data are tabulated in the Table. 3 below:

Table 3. Knot run-down test data

Exp #	Run-down force (kg)	
	Coated suture	Uncoated suture
1	0.28	0.39
2	0.20	0.54
3	0.26	0.42
4	0.22	0.49
6	0.18	0.44
7	0.19	0.28
8	0.21	0.26
average	0.22 ± 0.05	0.40 ± 0.14

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As can be seen from the above result, the coated sutures had lower run-down force when compared to the uncoated sutures.

8. Friction tests

The schematic of suture-on-suture testing set-up is shown in the fig. 9 below.

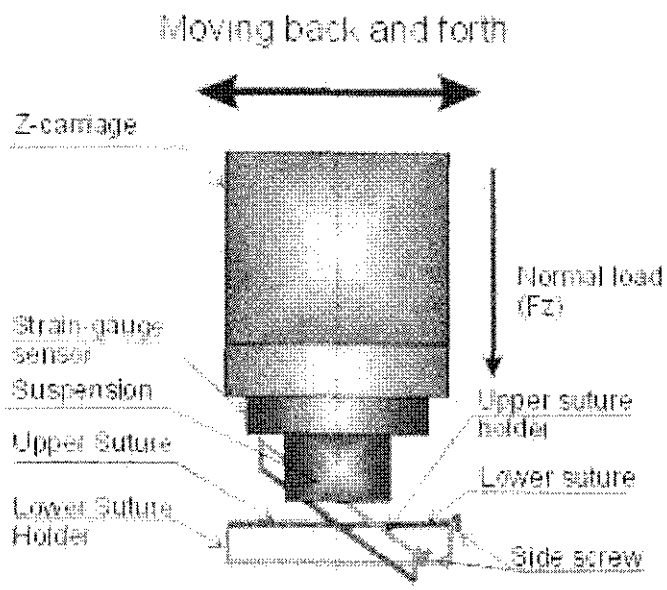

Figure 9. Test schematic for measuring suture-on-suture friction

A sample of suture was mounted and tensioned on the upper sample holder and another sample of the same suture was mounted and tensioned on the lower sample holder. The tension of both the sutures was adjusted using side screws to ensure constant tension for each suture, as shown in fig. 10. The upper suture was moved on the lower one back and forth with a reciprocating length of 3 mm at a frequency of 0.5 Hz under a constant normal load of 2 N (0.2 kg) for 200 seconds. A close-loop feedback loading mechanism ensured a constant normal force.

Both the applied vertical load and friction (shear) response force were continuously monitored and recorded during the tests.

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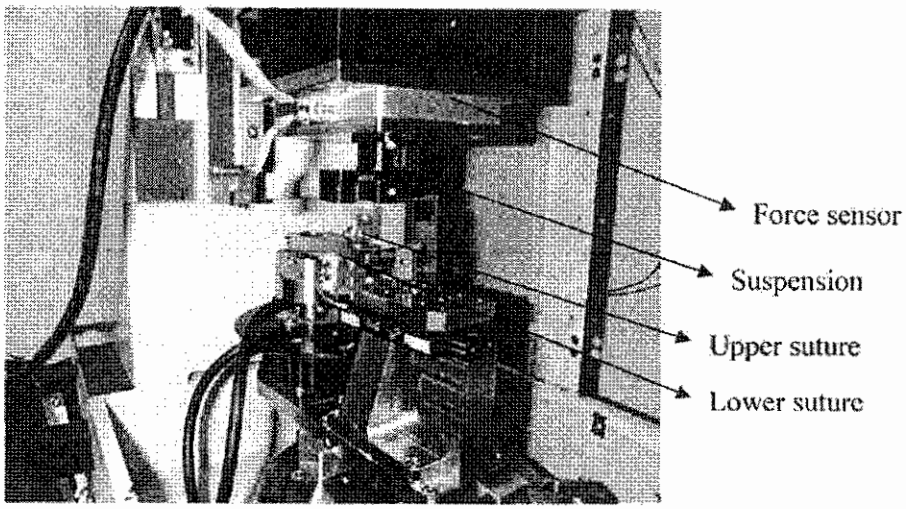

Figure 10. Set up of suture-on-suture friction tests

The coefficient of friction curves as recorded during the reciprocating tests are presented in fig. 11 below. The uncoated sutures had higher average coefficient of friction. The numerical data from the tests are noted and summarized in table. 4

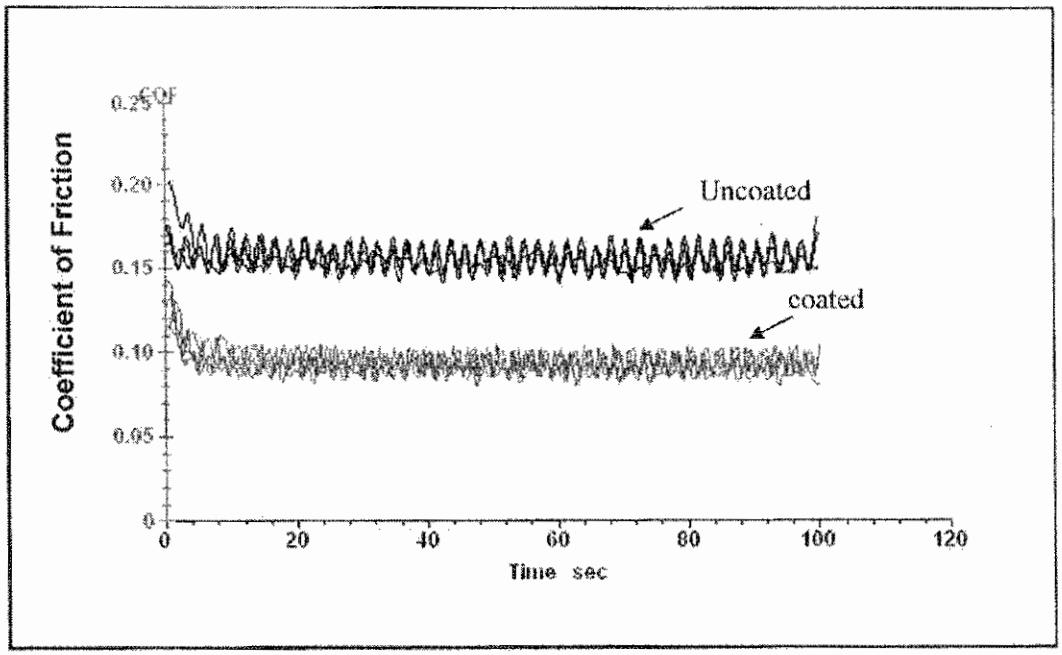

Figure 11. Typical Coefficient of Friction curves for Coated and Uncoated Sutures

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Table 4: Average coefficient of friction data from suture-on-suture tests

Exp #	Coefficient of Friction	
	Coated suture	Uncoated suture
1	0.09	0.15
2	0.10	0.17
3	0.08	0.16
4	0.10	0.16
5	0.09	0.16
6	0.09	0.16
7	0.09	0.17
8	0.10	0.17
Average	0.09 ± 0.01	0.16 ± 0.01

From the above results, it can be seen that the coated sutures have lower coefficient of friction when compared to the uncoated sutures. This result correlates well with the run-down force data in the previous section. The average coefficient of friction data is similar to the previous data [1, 6].

9. Chatter Data

Chatter is termed as the variation in friction during knot run-down and/or reciprocating friction tests. These variations are due to stick-slip process between the interacting suture surfaces when the knot is tied-down [5]. The difference between the maximum and the minimum friction coefficients, or amplitude of frictional auto-oscillations, is the measure of the chatter. Chatter data measured from both the knot run-down and the suture-on-suture friction tests are summarized in the table 5 below.

Table 5: Chatter data from knot run-down and suture-on-suture tests

Test #	Chatter data	
	Coated suture	Uncoated suture
1	0.009	0.013
2	0.009	0.017
3	0.008	0.013
4	0.008	0.013
5	0.010	0.012
6	0.012	0.011
7	0.008	0.014
8	0.010	0.019
average	0.009 ± 0.001	0.014 ± 0.003

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The chatter was higher for the uncoated sutures when compared to the coated ones. This result strengthens the conclusion from the previous results that coated sutures provide greater ease of handling during surgical use.

10. Tissue Drag Tests

The frictional force encountered during the passage of the suture through a tissue is termed as tissue drag. A 20-mm length of suture was pulled through a piece of leather at a constant rate of 1 mm/sec, while continuously recording the pulling force. The test procedure is based on the description provided in the previous works [7]. The leather piece was held in position using fixtures as shown in fig. 12. Two types of tests were performed: dragging the suture through the hole made with a needle and dragging the suture between two tightly clamped pieces of leather. In both cases, the upper end of the suture was attached to the UMT upper bracket providing the well-controlled motorized dragging action. The average drag force measured in both types of experiments was identical.

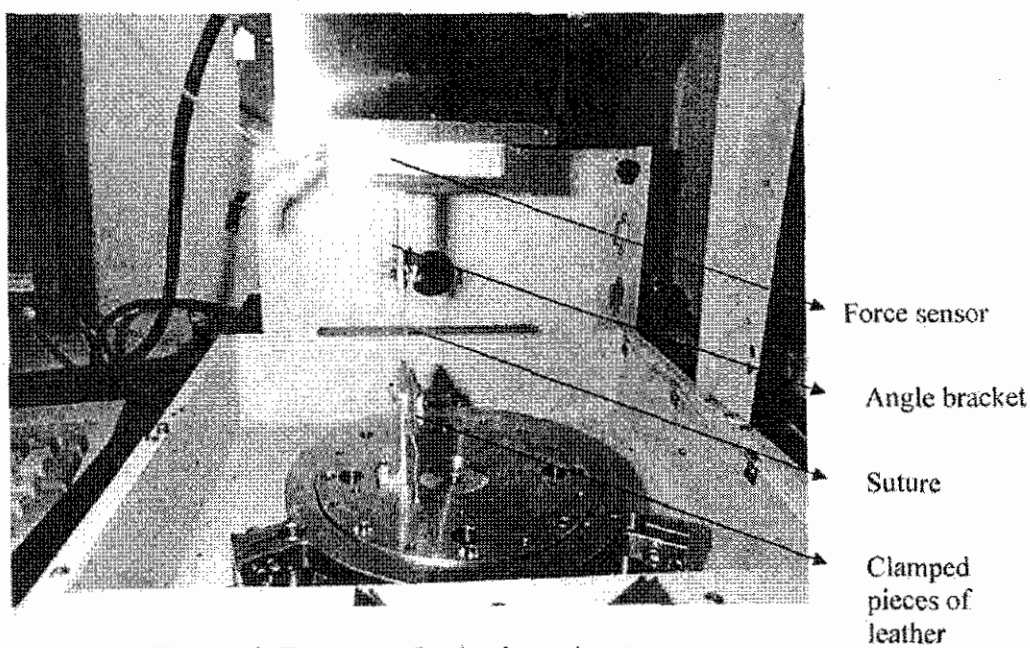

Figure 12. Test set up for the tissue drag test

Fig. 13 presents the force required to pull the coated and uncoated sutures. The highest force recorded gives a measure of the static drag force that was necessary to overcome in order to initiate the suture motion through the leather. The dynamic drag force was measured during the motion of the suture. The average static and dynamic drag forces are summarized in Table 6. The data are comparable to the previously reported results [1].

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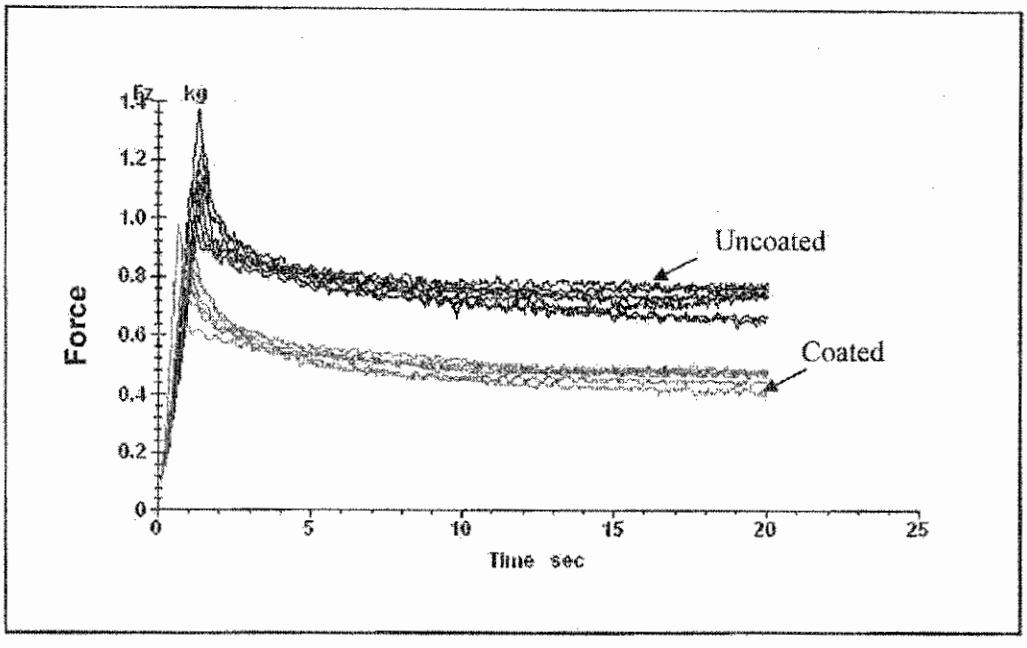

Figure 13. Typical force curves for coated and uncoated sutures.

Table 6. Drag force from the tissue drag tests

Exp #	Drag force (kg)			
	Static		Dynamic	
	Coated suture	Uncoated suture	Coated suture	Uncoated suture
1	1.10	1.15	0.55	0.74
2	0.86	1.20	0.52	0.78
3	0.71	1.19	0.41	0.84
4	0.68	1.39	0.46	0.91
5	0.97	1.10	0.46	0.85
6	1.11	1.19	0.58	0.64
7	0.90	1.13	0.51	0.77
8	0.92	1.13	0.50	0.72
Average	0.91 ± 0.20	1.18 ± 0.15	0.50 ± 0.11	0.78 ± 0.14

11. Microscopy Data

We have attempted to stud y the structure of the sutures with a digital optical microscope, attached to the same UMT tester, but the structure was undistinguishable. So, we utilized

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laboratory imaging services of a reputable local analytical lab AMER in Sunnyvale, California. Dr. Gitis brought samples of the uncoated and coated sutures to AMER and was present there all the time while their lab engineer Tony Lin performed SEM (scanning electron microscopy) imaging.

The obtained images are presented below in figures 14 and 15.

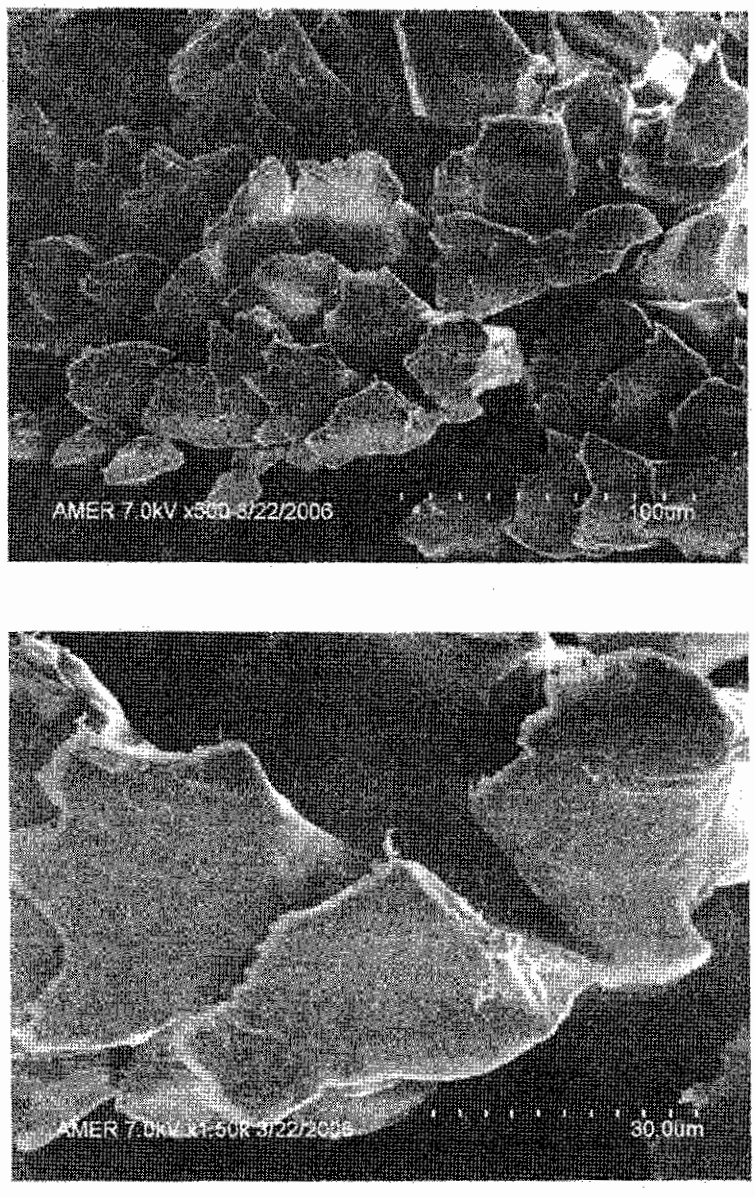

Figure 14. SEM Photos of the Coated Suture

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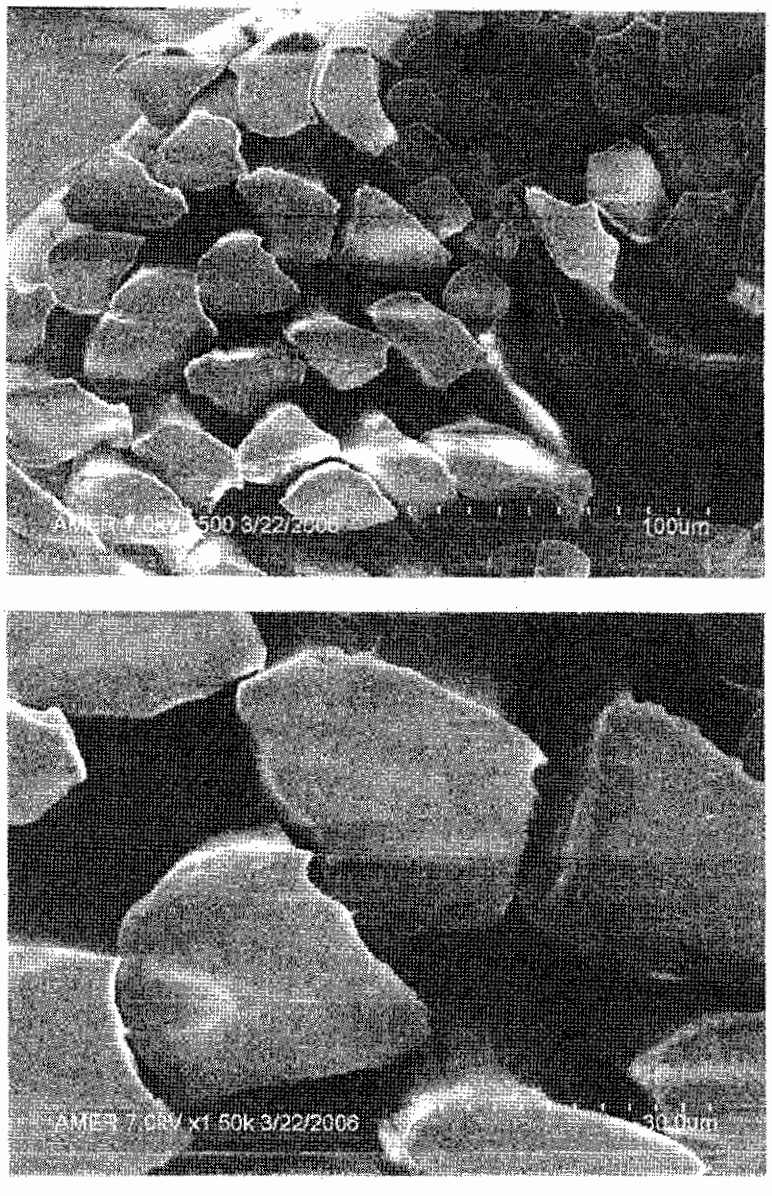

Figure 15. SEM Photos of Uncoated Sutures

12. Statistical Significance of Test Data

We used a common t-distribution statistical analysis, assuming the test data to be normally distributed The t-analysis assesses whether the means of two data groups are statistically

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different from each other. Then the test statistic (t-value) is calculated as [8, 9]:

$$t = \frac{Xu - Xc}{\sqrt{\frac{Vc}{Nc} + \frac{Vu}{Nu}}}$$

where X_c and V_c - mean and variance, correspondingly, of data for coated suture,
X_u and V_u - mean and variance, correspondingly, of data for uncoated suture,
N_c and N_u - number of tests for coated and uncoated sutures, correspondingly (N = 8).

The calculated t-values for all our test data are presented in Table 7 below.

Table 7. Comparison of t-values for data significance

Test	Coated		Uncoated		Experimental "t"-value	"T" threshold
	Xc	Vc	Xu	Vu	t	T
Stiffness	6.06 E-6	6.17 E -13	9.93 E-6	1.6 E -12	7.35	1.76
Slippage Strength	3.31	0.41	5.14	0.19	6.72	1.76
Untie Strength	2.52	0.2	3.66	0.54	3.72	1.76
Run-down Force	0.22	0.001	0.4	0.01	4.62	1.76
Friction	0.09	3.58 E -5	0.16	5.66 E -5	20.27	1.76
Chatter	0.009	1.58 E -6	0.014	6.91 E -6	4.63	1.76
Static drag	0.91	0.025	1.18	0.008	4.29	1.76
Dynamic drag	0.5	0.003	0.78	0.007	7.91	1.76

To make a conclusion that the difference between groups of data is statistically significant, the t-value should be larger when compared to a T-threshold calculated based on the degrees of freedom of the distribution and an error level. Degrees of freedom is calculated as [8]: DoF =

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$N_C + N_U - 2 = 14$. An error level of 0.05 (5%) is most commonly used. Based on the DoF and error level, the *T-threshold* is found from a standard t-distribution table [8, 9] to be $T = 1.76$.

As seen from the Table 7, the computed t-values of test data are much greater than the threshold T level, which allows us to conclude that the observed differences between coated and uncoated sutures are statistically significant.

Norma Gitis

Dr. Norma Gitis
President, Center for Tribology, Inc.
Chairman, STLE Technical Committee on Tribotesting

References:

1. George Rodeheaver et al, Journal of Surgical Research 35, 525-530 (1983)
2. Arthroscopy: The Journal of Arthroscopic and Related Surgery Vol. 16, No 2, (2000), pp 202-207
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EXHIBIT 3

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

-O-

DEPUY MITEK, INC., a Massachusetts Corporation,	:	Civil Action No.
Plaintiff,	:	04-12457 PBS
-vs-	:	
ARTHREX, INC., a Delaware Corporation, and PEARSALLS LTD., a Private Limited Company of the United Kingdom,	:	EXPERT DEPOSITION OF:
	:	ROBERT T. BURKS, M.D.
Defendants.	:	

-O-

Location: Mariott University Hotel
Salt Lake City, Utah

Date: June 7, 2006
3:00 p.m.

Reporter: Denise Kirk, CSR/RPR

-O-

other features that we talked about that you'd like to see in a suture but it does it in a way that it is a very strong suture which makes it much easier to work with.

Q. What other features that we talked about apply to FiberWire that you find beneficial?

A. I guess what I'm meaning is that the features we talked about such a handleability, passing through tissue, knot tying, etc., I find those features to be good, but what distinguishes it for me primarily is its strength.

Q. I'm just trying to be specific here. You said handleability, passing through tissue, knot tying, etc. When you say "etc.", what other features that we talked about apply to FiberWire?

A. I would say all the features that we talked about that you got done writing down. If FiberWire didn't meet those, then its strength might not be important; but since it does meet those and it is stronger than other sutures, then it becomes a preference.

Q. What suture did you use before FiberWire came onto the market?

A. For permanent suture we primarily used EthiBond.

Q. Let me rephrase the question. What suture did FiberWire wire replace in your practice?

A. It replaced EthiBond.

Q. Anything else?

A. Well, there are other companies that make sutures that are like EthiBond. EthiBond is almost like Kleenex where you say EthiBond and you actually might be using a suture from another company but we call it EthiBond. But that's primarily what it replaced.

Q. Is EthiBond manufactured by Ethicon?

A. Yes, but due to suture costs and bidding wars, there are other companies that make similar to EthiBond-type suture and we may have used those as well in the past.

Q. Is FiberWire stronger than Herculine?

A. I don't know the answer to that.

Q. Is FiberWire stronger than MaxBraid?

A. I don't know.

Q. Is FiberWire stronger than OrthoCord?

A. I don't know.

Q. Have you ever used Herculine?

A. I have.

Q. Have you ever used MaxBraid?

A. No.

Q. Have you ever used OrthoCord?

A. Yes.

Q. When have you used Herculine?

A. Herculine is a Linvitek product and so if I use a Linvitek anchor the Herculine comes with it and so that would usually be the time I'd use it.

Q. When do you use OrthoCord?

A. Same thing. OrthoCord is a Mitek product so if I use that I usually get the OrthoCord with it. I sometimes use three strands of OrthoCord when I don't need an anchor and I'm just sewing two tissues together.

Q. Do you like OrthoCord?

A. Yes.

Q. Why do you like OrthoCord?

A. I think for the same reason I like FiberWire. It's a very strong, hard-to-break suture.

Q. Does OrthoCord also have the characteristics of good handleability?

A. Yes.

Q. Does OrthoCord also have the characteristics of passing through suture well?

A. Yes.

Q. Does OrthoCord tie knots well?

A. Yes.

Q. Does it have good knot security?

A. Yes.

Q. Does it have good knot strength?

A. Yes.

Q. If we could turn to paragraph seven, please, in Exhibit 232. Are you there?

A. I am.

Q. You state: "I've been using FiberWire suture in my surgical procedures since 2001." What surgical procedures do you use FiberWire in?

A. I use FiberWire in most of the surgical procedures I do.

Q. Which ones are they?

A. I use it with shoulder replacement. I use it with rotator cuff repair. I use it with shoulder instability, knee ligament surgery.

Q. What knee ligament surgery do you use FiberWire in?

A. We use FiberWire whenever we want to repair torn ligaments back down to bone.

Q. You also say in exhibit seven of 232: "Most of my subjective use of FiberWire occurs during surgery and in the surgical environment, FiberWire is generally wet."

What do you mean by "subjective use"?

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it was my overall take from looking at them.
Q. Do you remember how many -- strike that.
Does a suture that has less friction when sliding that knot mean that the suture has better knot tie-down performance?
A. Not necessarily.
Q. Why?
A. Well, if you envision a perfectly smooth suture, for example, if you slide a knot it might slide very easily but it might also tend to not hold as well because there's not as much inherent friction in it.
Q. Does a smoother suture mean it has better tactile feel than a suture that is not as smooth?
A. I would say no, I don't know that I'd say it's a better tactile feel.
Q. Why did you use a surgeon's knot when you did the knot tie-down analysis in Exhibit 232?
A. I think what I would do is say that -- again, maybe my critique of the verbiage would be at fault. So I guess I wouldn't -- you know, we talked earlier about what a surgeon's knot is.
Q. Uh-huh?
A. And I probably didn't focus on it enough to say that they're not necessarily surgeons' knots as

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I described them.
Q. Okay, so why did you use the particular knots, then, that you used in the knot tie-down analysis?
A. I just tried to reproduce what I do in the operating room.
Q. In paragraph 11 in Exhibit 232 you state that suture A generally felt smoother than suture B. What do you mean by "generally"?
A. The differences between the sutures were subtle. I mean, they were not sharp, distinct. So I'm meaning that in comparing them, my take was that it was generally smoother.
Q. Were there any of the sutures in the tactile feel analysis where you couldn't tell the difference between suture A and suture B?
A. It was not my intent at the time in looking at the sutures to compare each strand side to side. My intent was to look at sort of spool A and spool B. So it was to get a feel of, in general, how do they feel between the two.
So I didn't take a strand and say is this one different? And is this one different? And go down through that five times, because I felt it was all the same suture.

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Q. But were there any where you couldn't tell a difference? I mean, it was pretty close?
A. Sure, it was pretty close.
Q. Let me rephrase. Were there any where you couldn't tell the difference between suture A and suture B?
MR. TAMBURO: Objection, asked and answered.
A. I don't remember specifically having ones that I would say I clearly feel a difference on this one and I clearly don't on the next one. It was a general feel of all of them.
Q. Dr. Burks, how would you describe your relationship with Ethicon?
A. I guess none.
Q. None? So you would say that you have a closer relationship with Arthrex?
A. Yes.
Q. What about could you describe your relationship with DePuy Mitek?
A. I have been a consultant with DePuy Mitek. Just this week I was helping on an educational course for DePuy Mitek reps. But I've had no product or anything like that with DePuy Mitek.
Q. You mean development product work?

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A. Yes.
Q. What was the educational course this last week that you helped with DePuy Mitek?
A. It was educating reps who go into the operating room and, you know, are helping surgeons with their materials, sutures, implants, what not, and how to handle the operating room environment, be appropriate and be helpful.
Q. The course was not on a particular DePuy Mitek technique or anything like that, it was --
A. It was not focused on a particular product but it was focused on helping reps better sell DePuy Mitek products.
Q. By being more professional in the operating room?
A. Correct.
Q. Is this the first time you have done that for DePuy Mitek?
A. This is the second.
Q. Other than those two courses, have you consulted with DePuy Mitek in any other courses?
A. Yes.
Q. What are those?
A. There was an educational course in Chicago and you are going to say when and I'm going to guess

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A. Yes.
Q. And now you are going to mark the suture sample that you took from Exhibit 284 with a flag?
A. Correct.
Q. Can you hand me the original sample sets back?
A. (Witness complies.)
Q. Also, I'm going to hand you DePuy Mitek Exhibit 234 which is a chart I'd like you to fill out if you could, please, and under the suture column put the numbers corresponding to the suture samples you've just cut, just 284, 285 and 286?
A. Fair enough?
Q. Fair enough.
A. Have we got a while?
Q. However long it takes you.
MR. TAMBURO: Are you representing that one of them is coated, one of them is not coated?
MR. FALKE: I'm not making any representations. They could all be coated, they could all be uncoated, could be a mix?
A. Can I use your notebook?
Q. Of course. What do you need?
A. I was going to use one of those metal rings.

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Q. Sure. First, can you do a tactile feel analysis on it? Can you tell the difference?
A. Kind of -- like I said, when you tie knots you combine that together.
Q. Can you explain what you are doing now?
A. I don't want to knock your little deal off, you know? I'm just getting a sense for how it slides and trying to put down a couple of throws.
Q. Which Exhibit Number are you working on?
A. I'm on 285.
Q. Okay. What type of knots are you throwing?
A. Half hitches.
Q. Now, can you explain what you are doing, Dr. Burks?
A. Same thing.
Q. With which exhibit?
A. 286.
Q. Are you doing the same thing you did with the previous one?
A. Yes.
Q. Same knot configurations?
A. Uh-huh.
Q. Can you tell a difference between the first two sutures, Dr. Burks, Exhibit 285 and --
A. 286.

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Q. And 286? Can you explain for the record please what you are doing now, Dr. Burks?
A. I'm tying 284.
(Discussion off the record.)
A. Okay. So where is my little sheet here?
Q. Based on what you've done so far, Dr. Burks, can you tell any difference between the sutures?
A. I feel like I do feel a difference.
Q. Okay. How would you describe that difference?
A. Well, I would say at the moment 285 seems a little smoother to me than 284. So I would say 285 is coated and 284 isn't coated.
Q. How sure are you of that?
A. I would not put my children's lives on it, but given the subjective feel.
Q. Is it a subtle difference?
A. It's a subtle difference.
Q. Can you explain, Dr. Burks, what you are doing now?
A. Just throwing knots. I would say 286 seems coated as well.
Q. If you had gloves on right now, would that change the confidence level you have in determining

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whether those are coated or uncoated sutures?
MR. TAMBURO: Objection, calls for speculation.
A. I think gloves can make a difference, yeah.
Q. How do they make a difference? The difference between the sutures is more subtle, right, with gloves because you don't have the contact like you described earlier with the skin?
A. Yeah. Again, this is obviously a very subjective feel test. Some of that feel comes from how the suture feels and some of it comes from how you feel when you slide a knot. So we're not talking rocks and water as far as differences and so. . .
Q. How would you qualify the difference that you just observed, based on your test?
A. When you say "qualify" are you asking for like an amount?
Q. How would you characterize the difference between the sutures?
A. Well the difference is, I think, subtle and there's no doubt in my mind that I could line up, you know, a hundred sutures and have error where I would say, you know, I think this one is one way or the other and make a mistake.

EXHIBIT 4

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

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The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

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MR. TAMBURO: Well, that's your opinion.
BY MR. BONELLA:
Q. Dr. Mukherjee, did you have -- did the samples when they came to you come on spools?
A. Frankly, I don't remember.
Q. You don't remember, okay.
Are you producing anything in response to the subpoena served on Dr. -- that was served on you to Dr. Gitis to bring things to the deposition today?
MR. TAMBURO: To bring things to this deposition today?
MR. BONELLA: Yes, yeah.
MR. TAMBURO: That I'd have to check. I'm not -- I didn't realize that you wanted things here today at this deposition that Dr. Gitis tested.
MR. BONELLA: Okay.
MR. TAMBURO: Where is -- where is that stated?
MR. BONELLA: I think it's in a subpoena to Dr. Gitis, but maybe there's some confusion.
MR. TAMBURO: And when was that served?
MR. BONELLA: Last week, as far as I know.
MR. TAMBURO: Do you know how that was

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served?
MR. BONELLA: I believe it was either FedEx or fax, I'm not sure.
MR. TAMBURO: Okay. Well, we'll look into it. If we have these materials, we'll bring them here today.
BY MR. BONELLA:
Q. Dr. Mukherjee, I am going to show you DePuy Mitek Exhibit 239. Do you recognize this as your expert report concerning the invalidity of U.S. Patent 5,314,446?
A. (Document review.) Yes.
Q. Okay. I'll show you DePuy Mitek Exhibit 240. Do you recognize that as the responsive expert report of Dr. Mukherjee concerning noninfringement of U.S. Patent Number 5,314,446 and other matters?
A. (Document review.) Yes.
Q. And I'll show you DePuy Mitek Exhibit 356. Do you recognize that as the rebuttal expert report of Dr. Mukherjee?
A. (Document review.)
MR. TAMBURO: If I could just interrupt, I don't recall ever seeing a subpoena to Dr. Gitis, but I do know that you asked for samples of the

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suture that Dr. Gitis tested, and I know that we have already produced to you the remaining suture that had not been tested, and we sent you half of what we received back from Dr. Gitis of what was actually tested. So, we sent that out to you last week, at the latest. So, that was produced already, those materials.
MR. BONELLA: Some of the materials were produced; others weren't.
MR. TAMBURO: What do you mean by that?
MR. BONELLA: Well, we are asking for all of them, so --
MR. TAMBURO: What do you mean by all of them? We sent you everything that we received from Dr. Gitis.
MR. BONELLA: You sent us -- I understand you just said you sent us half of what Dr. Gitis had from what he tested.
MR. TAMBURO: Right. So, you want the other half that we still have?
MR. BONELLA: Right.
MR. TAMBURO: Oh. So, you have half of what Dr. Gitis tested, but you want all of what Dr. Gitis tested --
MR. BONELLA: Correct.

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MR. TAMBURO: -- and you want us to have nothing?
MR. BONELLA: I didn't say that.
MR. TAMBURO: Well, that would be the result of what you're asking.
MR. BONELLA: No. We just want a chance to look at them and depose the witnesses on them.
MR. TAMBURO: Well, we sent you half of what we had, and if you chose not to bring it today, that's not our problem.
MR. BONELLA: I don't want to argue with you.
MR. TAMBURO: I don't want to argue with you either. This is not arguing.
THE WITNESS: Yes.
BY MR. BONELLA:
Q. Okay. If you could turn to your CV, please, which I believe is Exhibit 2 to --
A. Exhibit 239?
Q. -- Exhibit 239.
A. 239.
Q. You are an associate professor and coordinator of bioengineering for Louisiana State University Health Science Center. Is that correct?

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A. In Shreveport, yes.
Q. What do you mean by Shreveport?
A. LSU Health Science Center, there are two centers, one in New Orleans and one in Shreveport. This is Shreveport.
Q. Okay. So, do you work for the University -- Louisiana State University?
A. Yes.
Q. Okay. And what is your job as associate professor and coordinator of bioengineering?
A. I teach the orthopedic surgery residents and medical students.
Q. What do you teach?
A. Biomechanics and biomaterials.
Q. When you say you teach biomechanics, what do you mean by biomechanics?
A. You know the word, biomechanics.
Q. Excuse me?
A. You know the word, biomechanics, so that's what I teach.
Q. Well, I'd like your understanding of what you mean by biomechanics and what you teach.
A. We teach the testing of bone and bone implants and those kind of things, use applied biology and mechanics, that's the two terms

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biomechanics is made of.
Q. So, in biomechanics, you teach the testing of bone and bone implants?
A. And several other things. I can't tell you all of them.
Q. Well, generally, what does biomechanics that you teach encompass?
A. It's general principles of applying the forces in biological materials and you -- and you test them.
Q. So, the force is applied to bones and human structures?
A. Bones, ligaments, anything.
Q. Human structure?
A. Human; could be animal also.
Q. So, biomechanics, you're saying it's the study of forces applied to human or animal structure.
A. Um-hum.
Q. Does it include, say, the forces applied to implants?
A. The answer is yes.
Q. Yes. So, you teach that?
A. Yes.
Q. Okay. And how about -- biomaterials you

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said you teach, right?
A. Yes.
Q. Okay. And what do you teach with respect to biomaterials?
A. It is the material that could be used in the body.
Q. What type of materials do you teach about?
A. Orthopedic implants, sutures, medical devices.
Q. Okay. And how long have you taught with respect to biomechanics and biomaterials?
A. At this location, since 1992.
Q. Since '92. And you're an associate professor?
A. Yes.
Q. And you have been an associate professor since '92?
A. Yes.
Q. What's an associate professor as opposed to just professor?
A. It's one notch below professor.
Q. One notch below professor, okay.
And is it the entry level for a professor career, is associate professor?
A. No.

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Q. What's the first level?
A. Assistant professor.
Q. Assistant professor.
So, were you an assistant professor at some point?
A. No.
Q. You started as an associate professor in '92?
A. Yes.
Q. And you're an associate professor today?
A. Yes.
Q. Okay. How long does it typically take to become a full professor?
A. There is no set time.
Q. Well, typically in the field.
A. I cannot answer that question.
Q. You can't answer, okay.
Have you been reviewed for professor, full professor?
A. Yes.
Q. And why have you not made full professor?
A. I cannot answer that.
Q. You don't know?
A. I don't know.
Q. Have you had reviews from the university

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A. Yes.
Q. Okay, all right. When were you first contacted to provide some opinions in this case? Was that in February of this year?
A. That sounds right.
Q. Okay. And before February of 2006, had you done any work in this case?
A. No, no.
Q. Okay. And you did your first report on -- Exhibit 239 is your first report, on March 3rd, 2006?
A. That's correct.
Q. Okay. Where were you when you signed that report?
A. I was in Shreveport.
Q. Shreveport, okay.
Did you fax that signature page to the law firm?
A. That's correct.
Q. Okay. Tell me about the process of writing the report, Exhibit 239.
A. I -- we discussed at length about this and what my opinion is and my expert suggestion would be, and then they got it typed, sent me a fax, and I went over, made changes, and got it back again,

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look at it again, or sometimes I met them personally, and that's how the report was constructed.
Q. Okay. Do you have any of those communications with counsel still?
A. I didn't write anything.
Q. Well, no, they communicated with you. You didn't write anything?
A. No.
Q. Okay. You wrote nothing?
A. Right.
Q. Did you make any comments, written?
A. I think we went through it verbally, this sentence there, that sentence there, and that's what we did.
Q. Okay. And do you have any of those communications that they sent to you?
A. I don't know what communications you're talking about. In terms of this?
Q. The report, right.
A. I don't know whether I have it or I brought it here.
Q. No, I mean, do you have it, you know, in Louisiana or where you live or work?
A. You know, there's so little of that, like

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sometimes one page was faxed, not the entire report, because there were no changes in the others. So, I don't know whether I kept everything. I might have -- you know, some were left out, and I don't know where they are.
Q. So, you don't know whether you have that information or not?
A. Yeah.
Q. Okay. How about -- the next report is your responsive report, that's Exhibit 240, and you signed that one on March 24th, 2006, right?
A. Yes.
Q. And you signed that one in Louisiana, too?
A. Yes.
Q. And you faxed the signature page to the law firm?
A. Yes.
Q. Okay. And was the process for that -- writing the responsive report the same, communications from the law firm, and then you signed the final report?
A. Yeah, we discussed at length about this. In fact, we met face to face, and then we -- I advised my changes, doing all this.
Q. Okay. Were you present when they were

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actually writing the report?
MR. TAMBURO: Objection, vague.
THE WITNESS: You mean me in Washington?
BY MR. BONELLA:
Q. Well, when someone was typing the report, were you physically present?
A. No, I was not.
Q. How about for Exhibit 239, were you physically present when someone was typing that report?
A. No.
Q. Okay. When you were meeting with the lawyers to prepare Exhibit 239 and 240, were you discussing your opinions and what they would be and not putting pencil to paper, in other words? You were kind of orally discussing what your opinions were?
MR. TAMBURO: Objection, compound.
THE WITNESS: I -- this is my opinion, it's all here, but if you're asking me whether I literally typed it, no, I didn't.
BY MR. BONELLA:
Q. No. I'm just saying, or did you literally write out any of your opinions?
A. I didn't write out. Mostly verbally we

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Pearsalls?
A. No.
Q. In Exhibit 23 -- the first report, Exhibit 239, at the end, Exhibit 1, there's the documents reviewed and considered in connection with that report.
A. Yeah.
Q. Did you list all the documents reviewed and considered in connection with forming your opinions in Exhibit 239 in Exhibit 1 of Exhibit 239?
A. Yes.
Q. Okay. How about Exhibit 240, Exhibit 1, again, the documents reviewed and considered, did you list in Exhibit 1 to Exhibit 240 all the documents reviewed and considered in forming your opinions with respect to Exhibit 240?
A. Yes.
Q. Okay. And Exhibit 356, your rebuttal expert report, for Exhibit 356, did you list all the documents reviewed and considered in forming your opinions expressed in Exhibit 34 -- in Exhibit 356 in Exhibit 1 to that report?
A. Yes.
Q. Okay. Now, you have three reports, right?

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A. Yeah.
Q. So, they list all of the -- they list and describe all of the opinions that you have in this case?
A. That's correct.
Q. Okay. Do you have any opinions that you've formed subsequent to signing these reports with respect to this case?
MR. TAMBURO: Objection, vague.
THE WITNESS: No.
BY MR. BONELLA:
Q. Okay. Have you looked at any additional materials since you signed the last report, Exhibit 356?
MR. TAMBURO: Objection, vague.
THE WITNESS: Related to this case?
BY MR. BONELLA:
Q. Yes.
A. Okay. No.
Q. Are you or have you been asked to prepare another expert report in this case?
A. No.
Q. In forming your report or your opinions, you listed the materials that you reviewed and considered. How did it come about that you

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reviewed and considered those materials? Did you ask for all information bearing on an issue from the law firm or --
A. They supplied and I asked and I supplied some information.
Q. Okay.
A. So, that's how it worked. Mostly they supplied.
Q. Okay. Did you ask the law firm for all information bearing on an issue?
A. Yes.
Q. Okay. And you took their word that they gave you everything that was relevant to that information?
A. That's correct.
Q. Okay. The testing that Dr. Gitis did, were you present for that testing?
A. I was not present.
Q. Okay. The testing that Dr. Burks did, were you present for that testing?
A. No.
Q. I'm going to refer to the claims of the '446 patent today, when we talk about them, the ones that I think you have opined on are claims 1, 2, 8, 9 and 12. Is that right?

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A. That's correct.
Q. Okay. So, when we talk about -- can we just, for shorthand, refer to the claims of the '446 patent, and when we refer to the claims of the '446 patent, we will be referring to claims 1, 2, 8, 9 and 12. Is that okay?
A. That's fine.
Q. Because those are the only ones you have opinions on, right?
A. Okay.
MR. BONELLA: Let's take a short break.
VIDEOGRAPHER: We are going off the record at 11:39.
(A brief recess was taken.)
VIDEOGRAPHER: We're back on the record at 11:47.
BY MR. BONELLA:
Q. In forming the opinions in your responsive report, Exhibit 240, do you recall any other communications you received from anyone that you used in forming your report?
A. Other than are listed here?
Q. Right.
A. No.
Q. Did you see any drafts of Dr. Burks' report

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applied by Dr. Gitis?
A. You have to have constant diameter to meet USP; otherwise, the suture you cannot sell. Braid, monofilament, it doesn't matter.
Q. Well, no, sutures -- that's not true, is it? Sutures, if you measure along the range of a suture, its diameter is going to be different.
A. There will be -- within the range, there is a range, that's right.
Q. Right.
A. But you have to meet that -- so, diameter can be measured.
Q. Right.
A. And is measured.
Q. Right.
A. So that you meet the spec.
Q. Right. And in this test, the constant diameter was assumed, right?
A. Again, the diameter doesn't vary over a wide range so that these assumptions will be invalid.
Q. True or false: In this test, he assumed a constant diameter of 0.65 millimeters.
A. True.
Q. True, okay. Have you looked at -- have you

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ever measured the diameter of FiberWire along various lengths?
A. No.
Q. Okay. Do you know if it varies along the length?
A. It may. I don't know.
Q. You don't know. Did you ask for that to be measured?
A. No.
Q. Why not?
A. Because he's the expert. We relied on him, because he has tremendous experience in testing sutures for several companies, as you can see listed on the first page, so I relied on him, his decision.
Q. Are you not an expert in suture testing?
A. No.
Q. Okay. Doesn't the test that he performed -- well, let me back up.
He says at the top of page 3 for the pliability test.
A. Page 3, yeah.
Q. He says, "The suture was preloaded with a tension of 0.35 kilograms," right?
A. Correct.

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Q. Then he says, "The pulled suture --" I'm sorry, "The preloaded suture was then pulled at a force uniformly increasing at a rate of 0.33 kilograms per second."
Do you see that?
A. Right.
Q. What does that mean?
A. That means the rate of pulling the suture, the load -- you can do tests both ways, either -- either ways, either the constant load or constant elongation. This was done by varying the load.
Q. By varying the load?
A. Right, a kilogram per second.
Q. And elongation was constant?
A. Elongation also varied, because the -- these are setups in the machine, that you can vary the load or you can vary the elongation. So, what he did, he mentioned -- the way he measured is the loading by 0.5 kilograms per -- by 0.33 kilograms per second, and I'm not familiar with the setup, so I cannot tell you exactly how it is done.
Q. Okay.
A. But normally you do.
Q. From reading this, can you tell me how it was done, or would you need more information?

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A. No, reading this, you pull the suture at a different loading rate rather than rate of constant speed, so --
Q. I thought he says uniformly increasing the rate.
A. Right. That's why you have to --
Q. So, he's changing the rate at which he --
A. Increasing the -- see here, read that whole thing, "Preloaded suture was then pulled at a force, uniformly increasing at the rate of 0.33 kilograms per second."
Q. Okay.
A. So, the force is increasing, total force, when he is going at that rate.
Q. Okay. And he figured out -- then he measured the strength?
A. He measured the modulus of elasticity, which is the early part of the stress-strain curve, and that's what the E stands for. It is not the strength, but it is the early part of the stress-strain curve.
Q. Well, when you say the early part of the stress-strain curve, why is it just the early part of the stress-strain curve?
A. Because that's the property of the

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

v.

ARTHREX, INC., a Delaware Corporation

Defendant.

Videotaped Deposition of DEBI PRASAD MUKHERJEE

- VOLUME TWO -

Washington, DC

Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

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but -- and, you know, you measure the strength of the string whereas in bending, you do this way.
Q You do what way?
A And -- like you hold this and you bend. You know, the forces go perpendicular to the direction of the fiber. Now, nevertheless, this is what these people have done. They know what technique they used here.
Q Okay.
A I'm not really familiar with their equipment, so -- their setup, so this person, Norm Gitis, is the expert.
Q Okay.
A He's the person can answer all your questions, how it was done and what tests that it was used.
Q Okay. Now, the -- the bending test you used, did you -- if I understand your testimony, you're saying a tension test, normally a specimen is loaded and you pull longitudinally on the specimen, is that right?
A Right.
Q And you were saying a bending test, normally you --
A You --

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Q -- perpendicular --
A -- bend it.
Q Transverse wise.
Do you know which way the specimen in the pliability test that Dr. Gitis performed was loaded?
A I think it is a tensile test. That's what he did.
Q You think he did a tensile test?
A That's my assumption. Norm Gitis is a better person to tell you.
Q In a tension test, I think you said you pull longitudinally one direction. But don't you normally do it in two directions?
A No. Normally you do one direction.
Q In a tension test?
A Yes.
Q Why -- why did -- is -- why would -- why is -- why is it -- why do you do a tension test here then and call it a pliability test?
MR. TAMBURO: Objection. The witness already stated that he did not perform the tests and he doesn't know the details about the tests and your best person to ask is the person who did the tests, the expert who did the tests, Norm Gitis. You're welcome to ask your -- ask your questions, but he's

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already told you he doesn't know.
A This says -- in fact, you see the reference was given.
BY MR. BONELLA:
Q Right.
A The Rodeheaver, they followed the Rodeheaver's test. There's a reference to Rodeheaver, and it's a published paper and the procedure is used according to his paper. Again, Norman Gitis is the person to answer your question.
Q Can you tell me why it was okay to use this test for determine -- I'm sorry.
Can you tell me why it was okay to use the pliability tests that Dr. Gitis used to determine pliability for FiberWire?
MR. TAMBURO: Same objection. The witness is not an expert in these test procedures, and he's already told you that the person to speak with is Norm Gitis. To the extent you know the answer, you can answer.
A I answered your question before.
BY MR. BONELLA:
Q What is your answer?
A That I do not know.
Q Okay. Did you approve the pliability

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tests that he -- that he did? I'm sorry, I'll ask you that question. Did you approve the pliability tests that Dr. Gitis did before he did it?
MR. TAMBURO: Objection, vague.
A He's the authority. He decided on it and -- and we just did the -- we didn't measure pliability, all right? That is the extent of conversation I had. He decided the procedure and the technique.
(Exhibit No. 363 was marked.)
BY MR. BONELLA:
Q Okay. I'll show you DePuy Mitek Exhibit 363 -- it's Bates numbers CETR42 through 47 -- and ask you if you recognize the e-mail chain in Exhibit 363.
A Yes, I do.
Q Okay. And is the DMUKH@earthlink.net address, is that your e-mail address?
A KHE. There's no E there. DMUKHE at Earthlink.
Q What is your e-mail address?
A DMUKHE, but it doesn't have an E there.
Q Doesn't have an E? Right.
A Because there is no E there.
Q Right. Well, what is your e-mail? Your

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Q Not all eight sample curves are on there. Do you see that? For the coated and uncoated, it shows looks like four sample curves for the uncoated and three for the coated. I'm sorry, maybe it's three for the uncoated and --
A That's what I was looking --
Q Sorry, sorry.
A -- if you let me read this. That's what I was doing. Three for the uncoated.
Q And three for the coated?
A Right.
Q Okay. He tested eight samples?
A Yes.
Q Okay. Did you see the curves for the other five samples?
A Again, he reported the data. I did not see anything beyond what's in here.
Q Okay. For the knot strength at knot failure, do you see the coated and uncoated? See that?
A Yes.
Q Sample number 1, the uncoated, failed at 4.09, and the coated failed at 3.06, right?
A Knot failure? Yes.
Q Okay. So the -- sample number 1, the

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uncoated, had a higher knot strength according to that test?
A Again, I cannot make any comments on individual data. Has to be the average and the statistical analysis of the data. And again, Norm Gitis can explain these questions that you are asking to me. I do not know the answer.
Q Can you explain why sample -- see sample number 1? The uncoated -- uncoated has a higher value than the coated. Do you see that?
A Yes.
Q For knot failure. See that?
A Sample number 1?
Q Right.
A Yes. The uncoated is higher than the coated?
Q That's what the number looks like.
A Okay.
Q That number of 4.09 is higher than --
A I just want to make sure that's what you're referring to.
Q Right.
A Okay?
Q Okay. Now, if you go down and you see sample number 3.

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A Yes.
Q Sample number 3, the coated number, is 3.15 at failure and the uncoated is 2.42. Do you see that?
A Yes, I do.
Q So for sample number one, the uncoated failed at a higher value -- value, and for sample number 3, the coated failed at a higher value. See that?
A I see.
Q How do you explain that?
A I answered your question over and over again that I cannot answer the individual data. Norm Gitis is the person who can explain this. I only can see the averages. To my knowledge, that's the way to look at it, not individual data like you're doing.
Q Okay. It -- it's your opinion -- is it your opinion that the coating on FiberWire decreases the knot strength?
MR. TAMBURO: Objection, vague. Are we going by the same definition of knot strength as yesterday?
MR. BONELLA: The knot strength as reported in table 2 of Dr. Gitis' report.
A I have to look at the statistical analysis

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of these variations. Uncoated variations are a little higher than the coated so I'm not sure what the statistical averages showed. So again, Norm can answer the question.
BY MR. BONELLA:
Q Do you have an opinion of whether the coating caused the knot strength to either increase or decrease?
A No, I don't, because it -- it varies with the materials and everything. So I don't have a general opinion, no.
Q No, I'm -- not general opinion, I'm talking about the -- as -- based on the testing that's reported in table 2, do you have an opinion whether the -- the coating on FiberWire caused the knot strength to either increase or decrease as reported in table 2?
A Again, I have to look at the statistical analysis of these data. And again, Norm will -- will tell you that. And I'm not -- I am not really sure that I can answer your question. I cannot.
Q Cannot? Okay. Next test is the knot rundown test.
A Which page?
Q Page 7 of Exhibit 20. The CETR report.

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A Page 7, yes.
Q Okay. Are you familiar with how this test was performed?
A Not really. He's the expert. Norm Gitis is expert. He did what is procedure he used.
Q And the tests before that, the knot slippage test, were you -- are you familiar with how those tests were done?
A No.
Q Okay. The knot rundown test data that's in table 3 on page 8, do you see that?
A Okay, yes, I do.
Q Do you have an opinion as to whether the coat -- how the -- whether the coating affects -- I'm sorry, I'll ask the -- reask that question.
Do you have an opinion as to whether the FiberWire's coating affects the knot rundown --
MR. TAMBURO: Objection, vague.
BY MR. BONELLA:
Q -- based on table 3?
A No, I do not.
Q Okay. Did you ever see any of the graphs, any graph other than what's reported -- I'm sorry.
Did you ever see any knot rundown curves other than the ones reported in figure 8 that

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Dr. Gitis did?
A No, I did -- did not.
Q Can you explain why sample 1, coated suture, had a knot rundown of 0.28 in the table? Yeah, sample 1 had a knot rundown of 0.28 and sample 7 -- I'm sorry.
Can you explain why the coated, sample 1, had a rundown force of 0.28 and the uncoated, sample 7, had a rundown force of 0.28, which are the same?
A Same answer as before. I -- we -- I cannot explain any of the individual data. You have to ask Norm Gitis for the answer. I do not know.
Q The next test is a friction test. Are you familiar with how that test was performed?
A Again, Norm is the expert. That's what he did. I do not know.
Q Okay. Let me back up to the test before that again, the rundown --
A Where are you now?
Q I'm sorry, the rundown test.
A Page 7?
Q Still on page 8.
A Page 8.
Q Did you consider in your analysis whether the bending strength or pliability of the uncoated and

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coated sutures that Dr. Gitis tested could be determined from the knot rundown test that he did?
A No. Again, Norm Gitis is the expert. He knows the answer. I do not.
Q If the -- if the knot rundown tests and the knot slippage tests show that the --
A Now, knot rundown is page 8.
Q Right.
A And knot slippage is page 6?
Q Right.
If the knot slippage and knot rundown tests show that the coated suture is stiffer than the uncoated suture, how would you explain that?
A Again, Norm Gitis is -- is the expert. He can explain the data.
Q Are you an expert in explaining the results of this data that Dr. Gitis did and how it relates to FiberWire's coating?
A Not really.
Q Okay. In the friction test that he did, you see table 4, the friction test?
A Page?
Q Page 11 of CETR report.
A Okay.
Q See the friction data?

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A Yes.
Q Okay. See how the coated had an average of .09 and the uncoated had an average of 0.16? Do you see that?
A Sample number -- which one you talking about?
Q No, average.
A Average .009 and .014? Is that the one?
Q Sorry. I'm in the coefficient of friction, table 4, test at the top.
A I will check it. Okay.
Q Okay? See how the coated had a average of 0.09?
A Right, yes.
Q And the uncoated had 0.16?
A Right.
Q Have you seen any data to put other data of other sutures of what their coefficient of frictions were?
MR. TAMBURO: Objection, vague.
A I don't remember. I've seen my own eyes working suture but not -- I don't remember.
BY MR. BONELLA:
Q Do you remember what values you saw in your experience for coefficient of frictions for

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sutures?
A No, I don't.
Q Okay. Did you do any analysis of any of the CETR data to see how it compares to sutures in general to determine whether -- any effects on the material?
A No, I did not.
Q Okay. The chatter data on page 11 of the report that's CETR report, page 11, the chatter data.
A Yeah. Page 11. 16, 14 -- yeah.
Q Do you know how that data was determined?
A No. Again, Norm Gitis the person who answer the question.
Q Okay. See how sample 6 had a value of 0.012?
A 6, yeah.
Q For the coated?
A Yeah.
Q And for sample 6, the uncoated value was 0.011?
A Yes.
Q Are they about the same?
A Again --
MR. TAMBURO: Objection, vague.
A -- Norm Gitis can answer that question. I

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cannot.
BY MR. BONELLA:
Q You can't answer the question of 0.12 and 0.011 are about the same?
MR. TAMBURO: Objection, vague.
A No, I cannot.
BY MR. BONELLA:
Q You cannot?
Sample 5, uncoated, had a value of 0.012, right?
A Sample 5? Yes.
Q Uncoated. So sample 5, the value, uncoated, was the same as sample 6 value, coated. Do you see that?
A Yeah.
Q Can you explain why that's true?
A Again, the sample-to-sample variation, Norm Gitis will be able to explain why it is.
Q Can you -- do you have an opinion as to how coating affects the -- let me back up.
Based on table 5, did you have any -- do you have any opinions about how the coating affects the chatter of a suture -- of the FiberWire suture?
A No, but if you look at 16, where the data were compared statistically, that's where I make my --

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I made my opinion.
If you look at the stiffness, all the properties, coated and uncoated, differences, I -- I just wanted to see whether different or not. And I saw coated is different from uncoated. That much, I did. But other than that, I haven't done anything else. And Norm again who is the person to explain more about the individual data point as well as averages.
Q So you started by saying "no" to my question, so do you have any opinions about how the coating affects the chatter of a suture, of the FiberWire suture?
A The answer is no.
Q Okay. Next test is a tissue drag test. Do you know how that was performed?
A No.
Q Okay.
A Now, what page is that?
Q Page 12.
A Page 12. Yeah.
Q Did -- have you seen any curves other than what's shown in figure 13 for the tissue drag test results?
A No.

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Q In the drag force table, see the static columns on the left?
A Yes.
Q On the left-hand side, sample number 1, the coated suture had a static value drag force of 1.10. See that?
A Yes.
Q Number 5, sample number 5, uncoated, had a value of 1.10. Do you see that?
A Yes.
Q Can you explain why sample number 1, coated suture, and sample number 5, uncoated suture, have the same static value of drag force?
A Again, Norm Gitis can explain. I cannot.
Q Do you have any opinions about how the coating on FiberWire affects the drag force?
A No.
Q Next page is visual samples, pictures.
A Yes.
Q Page 14.
A Yes.
Q It shows four pictures on page 14. It should be Exhibit C to your report.
A 14 and 15, yes.
Q See the four pictures?

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446 AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

approximately 2-1/2 times easier to slide the knot down the suture.[1] In my opinion, these results demonstrate that coating materially affects knot tiedown of FiberWire suture.

In addition to the above described test, I have suggested tests of my own on coated and uncoated samples of FiberWire suture. Like the Arthrex test, the tests I suggested were objective in nature and also demonstrate that coating materially affects the handleability or pliability characteristics of FiberWire suture. The tests were conducted by the Center for Tribology in Campbell, California ("CETR"). The results are attached as Ex. 20. I understand that many of the world's leading suture manufacturing companies – including Ethicon and U.S. Surgical Corp. – use CETR to conduct various tests on their own suture.

Specifically, the tests conclusively show that the knot tie-down, chatter, coefficient of friction, knot security, pliability and tissue drag characteristics of FiberWire are each materially affected by the addition of coating. For example, the knot tie-down (knot run-down) test measures the force required to initiate movement of a half-hitch knot formed on the suture and also the force required to slide the knot down the suture. The results of the knot tie-down test are a function of the smoothness of the surface of the braid. The results of the knot tie-down test performed by CETR

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[1] The mean peak force required to initiate slippage of the knot on the uncoated suture was 32.0N, whereas only 12.7N were required to initiate slippage of the knot on the coated suture.

Dated: March 24, 2006

Debi Prasad Mukherjee, Sc.D.